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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

- - -

IN RE: NATIONAL : HON. DAN A.
PRESCRIPTION OPIATE : POLSTER
LITIGATION : MDL NO. 2804
:
APPLIES TO ALL CASES : NO.
: 1:17-MD-2804
:

- HIGHLY CONFIDENTIAL -

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -

December 20, 2018

- - -

Videotaped deposition of
DAVID LIN, taken pursuant to notice, was
held at the law offices of Drinker Biddle
& Reath, 105 College Road East,
Princeton, New Jersey, beginning at 9:18
a.m., on the above date, before Michelle
L. Gray, a Registered Professional
Reporter, Certified Shorthand Reporter,
Certified Realtime Reporter, and Notary
Public.

- - -

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5 Direction to Witness Not to Answer

6 PAGE LINE

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7

8 Request for Production of Documents

9 PAGE LINE

None.

10

11 Stipulations

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None.

13

Questions Marked

14

PAGE LINE

15 None.

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1 THE VIDEOGRAPHER: We are
2 now on the record. My name is
3 Henry Marte. I'm a videographer
4 with Golkow Litigation Services.

5 Today's date is
6 December 20th, 2018, and the time
7 is 9:18 a.m.

8 This videotaped deposition
9 is being held in Princeton, New
10 Jersey, in the matter of National
11 Prescription Opiate Litigation.

12 The deponent today is David
13 Lin.

14 All appearances will be
15 noted on the stenographic record.

16 Will the court reporter
17 administer the oath to the
18 witness.

19 - - -

20 ... DAVID LIN, having been
21 first duly sworn, was examined and
22 testified as follows:

23 - - -

24 EXAMINATION

1

2 BY MR. JANUSH:

3 Q. Hi, Mr. Lin. We had the
4 privilege of meeting briefly before this
5 deposition began. My name is Evan
6 Janush. Thank you appearing today for
7 your deposition. Have you ever been
8 deposed before?

9 A. Yes.

10 Q. How many times?

11 A. My recollection is
12 approximately two. These were over ten
13 years ago. So I think two -- two
14 instances.

15 Q. Was that in the same case or
16 different cases?

17 A. Different cases.

18 Q. And what were the nature of
19 those two cases?

20 A. I believe one was an
21 antitrust case and one was a patent case.

22 Q. Do you remember, when you
23 were deposed, were you employed by
24 Janssen at the time?

1 A. I was employed by, yes,
2 Janssen or another -- it might have gone
3 under a different name, but ti was still
4 within Johnson & Johnson.

5 Q. What were the products at
6 issue concerning those cases?

7 A. Hormonal contraception.

8 Q. In both cases?

9 A. My recollection is yes.

10 Q. In this case, when did you
11 first learn about the deposition?

12 A. I believe I was approached
13 regarding this deposition in the early
14 September -- either late August --
15 somewhere around Labor Day, is my
16 recollection.

17 Q. Do you remember who
18 contacted you?

19 A. Yes. It was one of the
20 attorneys for J&J.

21 Q. Do you remember whether that
22 was inhouse counsel or outside counsel
23 for J&J?

24 A. Inhouse counsel.

1 Q. Did you meet with anyone to
2 prepare for this particular deposition?

3 A. Yes, I did.

4 Q. Who did you meet with?

5 A. The gentleman sitting on my
6 left and Emilie. Ross and Emilie.

7 Q. On how many different dates
8 did you meet with Ross and Emilie?

9 A. We spent approximately two
10 days. Yeah, two days.

11 Q. Did you have separate --
12 were those -- those were in-person
13 meetings or telephone meetings?

14 A. Those were in-person
15 meetings.

16 Q. Okay. Were they full-day
17 meetings?

18 A. The better part of each day,
19 yes.

20 Q. And approximately how many
21 hours per day did you meet?

22 A. Somewhere between seven --
23 this is inclusive of all breaks and lunch
24 and everything. So probably seven hours,

1 seven to eight.

2 Q. Per day?

3 A. Per day.

4 Q. Did you meet with any
5 inhouse counsel for Janssen to prepare
6 for your deposition?

7 A. No.

8 Q. Did anyone from Janssen
9 communicate with you other than Janssen's
10 outside counsel, Ros and Emilie --

11 A. No.

12 Q. -- concerning your
13 deposition?

14 A. No.

15 Q. Without getting into any
16 specifics, were you shown documents to
17 prepare you in advance of your
18 deposition?

19 A. I was shown documents that
20 were representative of the types of
21 things that might be covered.

22 Q. Okay. Did you discuss this
23 deposition with anyone who is not your
24 counsel?

1 A. I mentioned it to my inhouse
2 attorneys, with my current employer, to
3 explain, just out of full disclosure,
4 that I would be out for a couple days.

5 Q. And your inhouse -- your
6 current employer is who?

7 A. My current employer is
8 Bristol-Myers Squibb.

9 Q. I'm going to try to run
10 through your employment history as
11 quickly as I can. I'm going to try and
12 spare you by ripping through as much as I
13 can myself, okay? I may ask for some
14 details here and there. So perhaps
15 you'll be able to help fill in the gaps.

16 I'm going to start with your
17 Janssen employment in 1997. And just for
18 demonstrative purposes, I'm going to take
19 some notes.

20 I understand that you
21 started in July of 1997; is that right?

22 A. That is right.

23 Q. Okay. And you started as
24 the assistant product director, sanitary

1 protection and over-the-counter personal
2 products company?

3 A. Yes.

4 Q. Is that right?

5 A. That's correct.

6 Q. All right. What did you
7 generally do as the assistant product
8 director for sanitary protection and
9 over-the-counter products?

10 A. These were entry level
11 marketing roles. They entailed basic
12 elements of running a consumer brand. So
13 I did things like forecasting,
14 promotional analysis, merchandising
15 strategy, market research.

16 Q. Okay.

17 A. Those are the big ones.

18 Q. And from there, I have it
19 listed that you became a product director
20 of women's health personal products from
21 August of 1999 to July of 2000. Is that
22 about right?

23 A. Yes.

24 Q. Okay. And what did you do

1 as a product director of women's health?

2 A. At that time I was
3 responsible for an over-the-counter
4 product that was in vaginal anti-fungals.

5 Q. What was that product?

6 A. That was Monistat.

7 Q. Okay. Incidentally, in this
8 position, did your performance get
9 reviewed?

10 A. Yes.

11 Q. Okay. And going back to
12 your assistant product director of
13 sanitary protection and over-the-counter
14 personal products, did your performance
15 get reviewed there as well?

16 A. Yes.

17 MR. GALIN: Mr. Janush, just
18 for the folks on the phone, I
19 think it's worth noting that
20 you're writing notes down on a
21 sheet using the Elmo as he's
22 speaking.

23 Sorry, folks.

24 MR. JANUSH: Is there a live

1 feed from which people can see
2 this video at the same time?

3 THE VIDEOGRAPHER: So they
4 do have a feed of the witness, but
5 not of the Elmo. The Elmo is
6 being recorded obviously.

7 MR. JANUSH: So for the
8 record, the Elmo is recording what
9 I'm doing. And everyone will have
10 access to this and be able to see
11 my notes.

12 BY MR. JANUSH:

13 Q. August 2000 to
14 September 2002, I have you listed as
15 director of marketing for Johnson &
16 Johnson Gateway, and that in this
17 position you managed the global marketing
18 and product development strategies for
19 J&J Gateway web-based products and
20 services; is that right?

21 A. That is correct.

22 Q. So J&J Gateway.

23 What are web-based products
24 and services?

1 A. In the context of Johnson &
2 Johnson Gateway, this was a suite of
3 capabilities that was designed to enable
4 product launches and -- across multiple
5 geographies, and it also served as an
6 electronic -- let me think of the right
7 word. This was early E-commerce, so it
8 was a way for hospitals and/or
9 distributors to place orders with the J&J
10 medical device business, basically
11 replacing fax by using an online order
12 system.

13 Q. Did you get reviewed in that
14 position? Did your performance get
15 reviewed?

16 A. Yes.

17 Q. The next position I show is
18 that you were product director for
19 women's healthcare for Ortho-McNeil
20 Pharmaceuticals from October 2002 to
21 June 2004; is that right?

22 A. That's right.

23 Q. Okay. What did you do as a
24 product director for women's healthcare

1 for Ortho-McNeil?

2 A. I was the -- there, I was
3 the lead marketer for a new entry in
4 hormonal birth control, called Ortho
5 Tri-Cyclen LO. That entailed promotional
6 strategy developing a forecast and making
7 resource allocation decisions for how the
8 commercial -- commercialization of that
9 product would take place.

10 Q. And did you have your
11 performance reviewed in this role?

12 A. My recollection is yes,
13 there was a performance review system.

14 Q. Okay. And when you have
15 your performance review, are you
16 typically presented with a document to
17 review and input your own comments as to
18 how you personally viewed your
19 performance for the year?

20 A. The my recollection is that
21 most of these, I would say, virtually the
22 entire time that I was employed by
23 Johnson & Johnson, there was an
24 electronic system where you entered your

1 objectives for the year, typically
2 between four and five objectives.

3 You comment on it at the
4 midpoint of the year. At the end of the
5 year, then your manager would typically
6 make a comment, a summary comment at the
7 end of the year. And they are captured.

8 Q. And did you have the
9 opportunity to review the end of the year
10 performance reviews throughout your
11 history of employment at Janssen, or the
12 various entities within Johnson & Johnson
13 that you worked for?

14 A. Typically the reviews were
15 done at the beginning of the new year.
16 And there would be a sit-down
17 conversation and it could last anywhere
18 from 30 minutes, to, my recollection,
19 45 minutes at the most. Yes.

20 Q. And so it's just, to be
21 clear, it's your recollection that for
22 every year, so I don't have to ask the
23 question, every year of your employment,
24 you were reviewed formally in writing

1 within some online system that allowed
2 you to capture your own notes and allowed
3 your supervisor to capture his or her
4 notes; is that right?

5 A. My recollection is almost
6 every year I would do that, yeah.

7 Q. And almost every year
8 someone would in turn review you?

9 A. Yes.

10 Q. Okay. The fifth job I have
11 listed is that you were a group product
12 director for urology. And that this was
13 for Ortho-McNeil Pharmaceuticals from
14 July '04 to July '06; is that right?

15 A. Yes.

16 Q. Okay. What did you do
17 generally in that role?

18 A. I was responsible for a --
19 for two marketed products in the urology
20 space. So it was simply managing a
21 larger portfolio than one product.

22 Q. What products were they?

23 A. Ditropan XL, and a product
24 called Elmiron.

1 Q. And the sixth job I have you
2 performing is director of marketing for
3 Ortho Women's Health and Urology. And
4 that would be from July '06 to
5 February '08; is that right?

6 A. That is right.

7 Q. Okay. What did you do
8 generally in that role?

9 A. That was an expansion of
10 responsibilities from urology, and the
11 women's health portfolio was added to my
12 responsibility set. So I had a broader
13 base of assets in terms of overall
14 oversight from a marketing perspective.

15 Q. So greater responsibility.
16 What does it mean to have a broader base
17 of assets?

18 A. It was a women's health
19 portfolio which had hormonal
20 contraception products, some vaginal
21 anti-fungals. And then there was the
22 urology portfolio that I mentioned
23 earlier. So Ditropan XL and Elmiron. So
24 I became responsible for that entire

1 group of assets.

2 Q. I have information listed
3 here that your 2007 business results
4 exceeded sales and profit commitments by
5 \$105 million and by \$40 million
6 respectively. Would you agree with that
7 statement?

8 A. Yes.

9 Q. Okay. And in this role you
10 co-promoted Elmiron with an alliance with
11 Bayer Healthcare; is that right?

12 A. That's correct.

13 Q. Okay. Next job I have is
14 that you were director of marketing,
15 institutional and hospital, for Janssen
16 Pharmaceuticals for -- between
17 February 2008 and December 2008; is that
18 right?

19 A. That is right.

20 Q. All right. Tell us about
21 what you did as director of marketing
22 institutional hospital for Janssen
23 Pharmaceuticals.

24 A. The company had submitted an

1 sNDA for a product in anticipation of it
2 being approved by the FDA. I was brought
3 in to prepare the organization for
4 launch. The product was not approved as
5 of August, and I worked within the
6 organization to close down the operation
7 in December.

8 Q. So did you receive
9 essentially a transfer to a different
10 group when you became director of
11 marketing, Janssen Pharmaceuticals, in
12 July -- January of 2009?

13 A. That was not a transfer.
14 That was simply within the same operating
15 unit.

16 Q. Okay. And you were in that
17 role as director of marketing for Janssen
18 from January 2009 through December 2009;
19 is that right?

20 A. That's right.

21 Q. Okay. What did you do in
22 this role?

23 A. In that role I was not
24 responsible for any product. I was

1 essentially asked to pull a -- pull a
2 team together, a cross-functional team to
3 envision what a more effective commercial
4 model could look like in the future. So,
5 typically called business transformation.
6 Working alongside consultants that I
7 hired, management consulting firms.

8 Q. And you were working on
9 creating a cross-functional team that was
10 not tied to any particular product at the
11 time?

12 A. That's correct.

13 Q. So this was, would it be
14 fair to say, akin to talent development
15 and creating a -- a unit that would be
16 implemented in the future?

17 A. No. It was -- it was more
18 accurately described as identifying what
19 are the potential capabilities that a
20 pharmaceutical company needed to evolve
21 in order to be actively and effectively
22 participating in healthcare marketing or
23 commercialization in the future.

24 Q. All right. And what did

1 you -- what did you -- what was the
2 upshot of that work?

3 A. The end result of that work
4 was identification of key capabilities,
5 specifically customer-facing capabilities
6 that needed to be evolved, strengthened,
7 if you will. And also made a
8 recommendation to strategically isolate
9 more mature brands in a different
10 business unit, because it required
11 different skill sets.

12 Q. Okay. And the next role
13 that I have is that you became the
14 director of marketing for pain for
15 Janssen Pharmaceuticals, January 2010
16 through October 2012; is that right?

17 A. That is right.

18 Q. All right. What did -- what
19 did you generally have responsibility for
20 as the director of marketing for pain for
21 Janssen in January 2010, in between
22 January 2010 and October of 2012?

23 A. In that role I was the brand
24 leader, akin to the previous positions

1 that I described, for a product called
2 Nucynta, and subsequently led the launch
3 of Nucynta ER, in the United States.

4 Q. All right. And Nucynta ER
5 is the Nucynta extended-release formula,
6 right?

7 A. That's right.

8 Q. Okay. What does -- what
9 does it mean to be the brand leader for
10 Nucynta?

11 A. The brand leader's
12 responsibility customarily involves,
13 you're the lead marketer and you
14 interface with key cross-functional
15 partners, such as sales, managed care,
16 business analytics and many other
17 enabling functions, to set a strategy for
18 a particular brand which typically
19 includes to what audience do you want to
20 engage, and how we differentiate this
21 product from others in the competitive
22 set.

23 Q. What does it mean to have
24 led the launch of Nucynta ER?

1 A. Leading the launch of a
2 product would have entailed anticipating
3 how -- or contemplating how the product
4 would be positioned, communicated prior
5 to launch. It would involve -- it would
6 involve definitely participation in label
7 negotiations with the FDA.

8 And then upon approval, be
9 responsible for marshalling the resources
10 of the overall organization to begin
11 promoting the product to a customer base.

12 Q. When you speak about label
13 negotiations, that's something that --
14 that you would have been involved in?

15 A. As a -- as a member of a
16 U.S. market, not directly responsible.
17 Those were regulatory discussions.

18 Simply, think of us as a --
19 not directly accountable but able to
20 provide input, just to make sure that
21 words are clear, labels are important in
22 the sense that they -- they're enduring
23 documents, so it's to make sure that the
24 clinical trials that were used as the

1 basis of approval, just to make sure
2 nomenclature is correct, that there's no
3 confusing terms, basically.

4 So as a marketing leader,
5 we're not directly responsible but you
6 have input into ensuring that we're using
7 the right words.

8 Q. I'm just going to take some
9 notes.

10 And in terms of marshalling
11 resources to begin promoting, can you
12 expand on what that means?

13 A. In the context of any
14 pharmaceutical product, this one
15 included, it would be -- we have an
16 intended audience, because these are
17 the -- this is the audience for whom we
18 feel would be the adopters of a new
19 product, where we feel like we can make
20 inroads by getting them to use our
21 product versus someone else's. And so
22 very simply it's what's the relevant
23 audience where we think we can make an
24 impact.

1 And then marshalling
2 resources really pertains to, if you've
3 identified that audience, how many can I
4 -- it's not reasonable to get to all of
5 them. So of the ones that you can get to
6 with the sales reps that you have ability
7 to access, what's a -- what's a middle
8 ground there in terms of
9 commercialization.

10 Q. So strategizing how to use
11 sales force to reach doctors?

12 A. Correct.

13 Q. Okay. Who were your key
14 direct reports in this time period as
15 director of sales and marketing -- excuse
16 me -- director of marketing between
17 January 2010 and October 2012?

18 A. The team certainly evolved
19 during that period. So could you
20 clarify? Do you -- are you asking me to
21 list names of people who were direct
22 reports?

23 Q. Yeah, who were key direct
24 reports that worked with you and worked

1 under you, in executing the leading of
2 the launch and marshalling resources to
3 promote?

4 MR. GALIN: Objection to
5 form.

6 THE WITNESS: In the -- in
7 the period of 2010, 2011, this is
8 prior to the launch of Nucynta ER.
9 This was just during promotion of
10 Nucynta.

11 Key direct reports would
12 have included Dave Moore, Nithya
13 Desikan, Ron Kuntz, Patricia Yap.
14 And I'd like to just clarify that
15 some of these folks that I'm
16 listing, it's possible that they
17 would have been a direct report to
18 a direct report. So I'm going to
19 speak generally about the brand
20 team. But these are some folks.

21 Lisa Ferguson, Kanitha
22 Burns, Lisa Bianciani, Dominic
23 Lazzaro, Frank DeMiro, and again
24 for clarity, I'm listing names of

1 people who have been on the brand.

2 I cannot be exactly clear as to

3 their tenure and which years.

4 It's quite a long time ago.

5 BY MR. JANUSH:

6 Q. And the next role that I

7 have you as performing is director of

8 sales and marketing, neuroscience/pain at

9 Janssen Pharmaceuticals, October 2012

10 through December 2013; is that right?

11 A. That's right.

12 Q. What did you do in this role

13 generally as director of sales and

14 marketing for neuroscience/pain for

15 Janssen?

16 A. Essentially it was the

17 marketing job that I just described for

18 you. And had expanded responsibility to

19 include a specialty sales force which was

20 a complete change out of our selling

21 structure in 2013. So I had -- the main

22 difference is I bolted on sales to my

23 responsibility.

24 Q. Okay. And was this a board

1 level role to be the director of sales
2 and marketing for the department of
3 neuroscience and pain?

4 MR. GALIN: Objection to
5 form.

6 THE WITNESS: The terms that
7 are used here is that, every
8 operating unit within -- let me
9 clarify. Most of the larger
10 operating units had a
11 cross-functional team of leaders,
12 so direct reports to the president
13 of the business unit constituted a
14 management board that was
15 responsible for the day-to-day
16 operations of that unit.

17 So that's why I wanted to
18 clarify what board level means,
19 board level meaning of an
20 operating unit. But that was not
21 a unique thing relative to me.

22 Other brand leaders within
23 that business unit, were also
24 members of that management board,

1 along with cross-functional
2 leaders.

3 BY MR. JANUSH:

4 Q. And who was the president of
5 neuroscience and CNS that you reported
6 to?

7 A. In which year?

8 Q. Sorry. October 2012 to
9 December 2013.

10 A. The president of the
11 business unit at the time was a gentleman
12 by the name of Michael Yang.

13 Q. And I have notes stating
14 that in this position you provided
15 general management leadership for a
16 120-person commercial team, including
17 sales, marketing, market access, and
18 patient assistance and sales training.
19 Is that accurate?

20 A. Yes.

21 Q. And I have additional notes
22 stating that you drove total prescription
23 share growth through the four months
24 following the new specialty sales team

1 formation. Is that right?

2 A. In the context of -- yes, we
3 organized a new selling structure that
4 was put in place in January 2013, and it
5 was during that time, yes, that -- that
6 references the right period, yes.

7 Q. And we're going to get into
8 that a bit further down the road. That
9 new sales team that you're speaking to is
10 the specialty pain force, right?

11 A. That's right.

12 Q. And I also have notes
13 stating that you -- when you led that new
14 standalone business unit, the specialty
15 pain force, that you exceeded -- your
16 group exceeded the 2013 business plan
17 commitment, 102 percent to forecast and
18 thereby delivering plus 2 percent
19 operational growth with a higher profit
20 contribution, in the face of a flat
21 category and multiple competitive
22 entrants to the market.

23 Would that be accurate?

24 A. Yes, that's accurate.

1 Q. And when we speak about
2 multiple competitive entrants to the
3 market, we're speaking about other
4 companies that were introducing opioid
5 products to the market at or around the
6 same time that Nucynta ER was being
7 introduced; is that right?

8 A. That's right.

9 Q. And I have further notes
10 indicating that you championed the pain
11 franchise evolution to this specialty
12 focus business unit. Was this specialty
13 focus unit, this is again referring to
14 the pain force; is that right?

15 A. That's right. Not only the
16 pain force, but the general composition
17 of the business was different than in the
18 prior years, meaning it was not one of
19 many products in a bag. It was reduced
20 to roughly 90-person sales organization,
21 a much smaller infrastructure.

22 MR. GALIN: I don't -- I'm
23 new to the Elmo process. But just
24 for the record I should note that

1 you do as you want in your notes,
2 but it doesn't quite capture the
3 complete answer that he gave.

4 MR. JANUSH: Right. These
5 are -- this is demonstrative. And
6 the transcript will always exist,
7 as will the video.

8 MR. GALIN: That's fine. I
9 just want --

10 MR. JANUSH: I can only do
11 the best that I can do while --

12 MR. GALIN: I'm impressed --

13 MR. JANUSH: -- listening
14 and writing.

15 MR. GALIN: I'm impressed
16 you're keeping up as well as you
17 are.

18 MR. JANUSH: Thanks.

19 BY MR. JANUSH:

20 Q. And my notes also indicate
21 that you oversaw the sales force strategy
22 development, hiring, training, and the
23 incentive compensation design. Would all
24 of that be correct as well?

1 A. That is correct.

2 Q. I'm just going to take some
3 notes on that.

4 (Whereupon, a discussion was
5 held off the record.)

6 MR. JANUSH: I think it's
7 fairly mundane notes.

8 MR. GALIN: The question is
9 if folks want to take a break
10 right now just to see if we can do
11 that. I don't want to throw
12 off --

13 MR. JANUSH: I'm willing to
14 accommodate that to look into
15 whether that can be done. We can
16 go off the record.

17 MR. GALIN: Shall we take a
18 brief break allow people on the --
19 to see if we can accommodate folks
20 on the phone?

21 THE VIDEOGRAPHER: Sure.
22 Yeah, I can't make any promises.
23 But I'll try to see if I can send
24 out a feed.

1 The time is 9:52 a.m. Off
2 the record.

3 (Short break.)

4 THE VIDEOGRAPHER: We are
5 back on the record. The time is
6 10:00 a.m.

7 BY MR. JANUSH:

8 Q. Okay. Before we went on
9 break, we were talking about some of your
10 last positions, specifically the sixth
11 position, director of marketing for pain,
12 and the seventh position, director of
13 sales and marketing neuroscience pain.

14 I want to just make sure
15 that I break these two positions down
16 with respect to asking the question I
17 asked earlier about performance reviews.

18 Were you -- was your
19 performance reviewed, to your
20 recollection, when you were director of
21 marketing for pain at Janssen?

22 A. Yes, my recollection is we
23 did have performance reviews.

24 Q. Okay. Who would have

1 reviewed your performance when you were
2 director of marketing for pain at
3 Janssen?

4 A. Are you asking me for who
5 would --

6 Q. The person, the --

7 A. The -- the specific name of
8 the person?

9 Q. Yeah. Like, who would your
10 boss have been that would have been
11 reviewing the director of marketing
12 position?

13 A. It would have -- there
14 was -- in that -- in those three years I
15 probably had three different managers.

16 Q. Okay.

17 A. So it would have included,
18 in 2 -- my 2010 review would have -- I
19 just want to clarify that I -- the dates,
20 the exact date and year could be wrong.
21 But in order -- the right order I think
22 was Kimberly Park, who was vice president
23 of sales and marketing for internal
24 medicine.

1 The second one might have --
2 would -- would have been Kati Chupa, who
3 was the vice president of marketing for
4 anti-infectives, the GI, gastrointestinal
5 business, and also pain.

6 And the very last review in
7 that role would have been Vanessa
8 Broadhurst, the president of internal --
9 Janssen internal medicine.

10 Q. Okay. And with regard to
11 the reviews that would have been
12 performed by Kimberly Park, by Vanessa --
13 by Kati Chupa, and by Vanessa Broadhurst,
14 you would have had an opportunity to see
15 those formal reviews and sign off on them
16 after they were completed by your
17 supervisors?

18 A. Yes.

19 Q. And moving forward to the
20 position as director of sales from
21 October 2012 to December 2013, who would
22 have reviewed you for that slightly more
23 than one-year period?

24 A. I'd like to clarify that

1 that role was director of sales and
2 marketing.

3 Q. Sorry. Director of sales
4 and marketing, yes.

5 A. That review would have been
6 conducted by Michael Yang, my supervisor
7 during that year.

8 Q. Do you remember being
9 reviewed by Michael Yang?

10 A. My recollection is yes, I
11 recall being reviewed by -- by Michael.

12 Q. Okay. How'd that review go?

13 A. Can you be more specific?

14 Q. Sure. Was it a positive
15 review, a mid -- a midlevel --
16 middling -- middle of the road review, or
17 a negative review?

18 A. I think I would characterize
19 it as positive, as I would characterize
20 almost all my reviews at J&J.

21 Q. Okay. Do you remember what
22 your -- what your bonus targets were for
23 2000 -- 2012 to December 2013?

24 A. No, sorry.

1 MR. GALIN: Objection to
2 form.

3 BY MR. JANUSH:

4 Q. Do you remember what your --
5 you don't remember what your targets were
6 as compared to your base comp?

7 A. It's -- I'd like to clarify
8 for the record. I haven't been at J&J
9 for some time.

10 Q. I understand.

11 A. Numericals around targets,
12 those were unique to the band, the job
13 band. But I can't -- I can't tell you
14 exactly what numbers they were.

15 Q. What led to your transition
16 from the director of sales and marketing
17 position in neuroscience and pain group
18 at Janssen to your role as vice president
19 of marketing global franchise
20 organization in January of 2014?

21 MR. GALIN: Objection to
22 form.

23 BY MR. JANUSH:

24 Q. I could ask first -- the

1 preliminary question.

2 Is it correct that in
3 January of 2014 you transitioned to the
4 vice president, marketing, global
5 franchise organization?

6 A. That's correct.

7 Q. What led to that transition?

8 A. At the most basic level,
9 it's career development.

10 Q. Okay. Is there anything
11 happening in the pain market with respect
12 to Nucynta that led to the transition out
13 of the role of director of sales and
14 marketing in neuroscience and pain?

15 A. No, sir. The -- if you look
16 at the context of the different roles
17 that I've held, we were entering the time
18 when I had decided it was roughly three
19 and a half to four years on one business,
20 and I was given an opportunity to move to
21 a different sector of the company at a
22 higher level. And those are few and far
23 between. And so I entered the process
24 and was selected for the role, and so I

1 moved.

2 Q. Incidentally, was it during
3 that tenure between January 2014 to
4 April 2015 when you were in that new and
5 more substantial role, I would say, that
6 Nucynta was -- efforts were being made to
7 sell Nucynta?

8 A. I read about -- so when I
9 moved, let me clarify, first I read about
10 the sale through my Apple phone on the
11 stock ticker. Once I moved sectors from
12 Janssen into the consumer business, for
13 all intents and purposes, it's a
14 different world.

15 So I was in a completely new
16 business, in a global role, not the U.S.
17 role. And so, yes, I learned about it --
18 I learned about it after it happened.

19 Q. What led you to -- I
20 understand that you were separated from
21 Janssen in April of 2015; is that right?

22 A. That's not right. I was
23 separated -- I separated from Johnson &
24 Johnson Consumer companies in April of

1 2015.

2 Q. Okay. What does it mean to
3 have separated from Johnson & Johnson
4 Consumer companies?

5 A. The consumer sector was
6 going through a restructure. So all of
7 the roles, like the roles I had, the role
8 I held, which was global in scope, were
9 being restructured to become regional
10 roles. And as a result, I was informed
11 that in 20 -- I was -- at the end of 2015
12 that role would be regraded from vice
13 president to senior director.

14 At that point you're given
15 an option of take -- take the re-scoped
16 role, or you can opt for a package,
17 separation package, and move on. I chose
18 the separation package.

19 Q. And your separation
20 agreement has been produced before your
21 deposition.

22 A. Yes.

23 Q. Was part of that valuation
24 based on your 17 or so years of service

1 to the company?

2 A. My understanding is it's a
3 formula based where you are compensated
4 for unused vacation days, and some
5 formula based on years of service.

6 Q. Okay. Fair to say that
7 we've covered your employment history on
8 a broad strokes level from when you
9 started with a Johnson & Johnson entity
10 to when you were separated in April of
11 2015?

12 A. I hope I've answered all
13 your questions.

14 Q. I'm asking whether we have
15 accurately covered your employment
16 history on a broad level?

17 A. Yeah, I have no other roles
18 within J&J.

19 Q. Thanks for clarifying that.
20 Okay.

21 Moving on to some
22 substantive matters, I hope. Thank you
23 for working with me to get your
24 background information out of the way.

1 I have a document Bates
2 marked JAN-MS-00448838. I am marking it
3 as Exhibit 1.

4 (Document marked for
5 identification as Exhibit
6 Janssen-Lin-1.)

7 MR. JANUSH: As a courtesy,
8 wherever I could, we put a cover
9 sheet on top of the document. We
10 can peel that out and not count it
11 as part of the exhibit. I'm sure
12 you'll agree. I did it to make it
13 easier so no one is searching for
14 where these documents are.

15 MR. GALIN: I appreciate
16 that.

17 MR. JANUSH: I have a copy
18 for counsel as well.

19 MR. GALIN: Thank you.

20 BY MR. JANUSH:

21 Q. This document is titled
22 business analytics marketing research
23 plan. It appears to be sent from you.
24 And it's addressing the subject of

1 Nucynta ER qualitative messaging study.

2 Excuse me. It's from Mike

3 Hanlon to you. Who was Mike Hanlon?

4 A. Question for clarification.

5 I'd like to answer who Mike Hanlon is

6 first, but then will you give me some

7 time to review the document?

8 Q. Absolutely.

9 A. Okay. Mike Hanlon was the
10 market research leader for Nucynta.

11 Q. Okay. Ready?

12 A. Yes.

13 Q. Okay. I'm not seeking to
14 delve too deeply into this document. I'm
15 trying to understand as a general
16 concept. This is a memo that is
17 documenting the concept that, "The
18 Nucynta ER launch team had recently
19 completed market research which
20 identified the creative concept that will
21 move forward in various promotional
22 executions"; is that right?

23 A. I agree with you, that's
24 what it says.

1 Q. Okay. And it looks like,
2 based on the next sentence, that,
3 "Results from a quantitative assessment
4 of 39 potential messages produced a
5 subset of the most compelling efficacy,
6 safety, tolerability, and MOA messages."

7 MOA stands for mechanism of
8 action; is that right?

9 A. That's my understanding,
10 yes.

11 Q. Okay. And skipping down to
12 the second paragraph. It states, "Upon
13 completion of this phase, these messages
14 will be integrated with the concept and
15 the overall message flow will be
16 developed and tested. Ultimately, this
17 output will inform brand and molecule
18 messaging at launch."

19 Do you see that?

20 A. Yes.

21 Q. In your own words, can you
22 describe what a -- what this qualitative
23 message study was seeking to achieve?

24 A. Very simply, a qualitative

1 message testing would seek to understand,
2 of all the things that one could
3 communicate about a product, what would
4 be the most compelling to differentiate
5 it in the mind of an audience, which I
6 need to just clarify here.

7 It looks like, it says here
8 obtain feedback from HCPs. So that would
9 be in the minds of a doctor or a nurse,
10 how would we actually break through the
11 clutter.

12 Q. And what -- more
13 specifically, the group that was studied
14 with approximately 40 total interviews,
15 if we look at methodology at the bottom,
16 or near the bottom where I'm
17 highlighting, included 50 percent of
18 PCP -- that's primary care physicians,
19 right?

20 A. Yes.

21 Q. 30 percent of the group
22 would be pain specialists that would be
23 interviewed, right?

24 A. Yes.

1 Q. And 20 percent would be a
2 mix of neurologists, rheumatologists,
3 oncologists, and surgeons.

4 Do I have that right?

5 A. Yes.

6 Q. Okay. And it says,
7 "Recruited from the ER target list."

8 What's the ER target list?

9 A. So I don't have that target
10 list in front of me. What I would
11 speculate, based on the fact that this is
12 pre -- it's mentioning prelaunch. The --
13 if it was prelaunch, I am conjecturing
14 that the ER target list would have been a
15 set of prescribing physicians in the
16 United States that wrote long-acting
17 opioids, and it was a starting point of
18 these are the potential -- these are the
19 particular audiences that the brand would
20 seek to engage upon launch.

21 For clarity, that target
22 list prelaunch is probably bigger than
23 when you actually get to a launch,
24 because when you actually get to a

1 launch, there is constrained resources.

2 You're limited by the capacity of the
3 sales force to actually reach them.

4 But this is the logical
5 starting point. So I think what the memo
6 is trying to just convey in that sentence
7 is that you would want to recruit people
8 from research that you could conceivably
9 be interacting with in the future.

10 Q. Okay. At the bottom, it
11 says, "Action standard, results of this
12 research will be used to determine the
13 most clear and compelling message
14 elements that will be used to
15 successfully and appropriately launch
16 Nucynta ER."

17 Do you see that?

18 A. Yes.

19 Q. Did -- did -- are you aware
20 of other instances in which Janssen went
21 out and hired a third party, as -- as in
22 this case, it looks like it's Susan Wyant
23 of the Dominion Group, to conduct what --
24 what I understand is referred to as

1 segmentation studies?

2 A. So can you repeat -- are you
3 asking if this is a segmentation study?

4 Q. Well, first of all, is this
5 a segmentation study, or just a message
6 study?

7 A. My understanding of this,
8 based on the -- what's available here is
9 that this is purely a recommendation
10 briefing me on the fact that we're going
11 to do some market research.

12 Q. Okay. And it's called a
13 study in objectives, right?

14 A. Yes.

15 Q. And it's to identify the
16 most clear and compelling way to
17 communicate key efficacy, safety,
18 tolerability and MOA messages, right?

19 A. Yes.

20 Q. And you are specifically
21 seeking to identify the pain and patient
22 types that healthcare practitioners would
23 treat with Nucynta ER and why. Is that
24 also right?

1 A. Yeah, I'm reading what
2 you're showing me, yes.

3 Q. Okay. And you're seeking to
4 gain insight into current attitudes
5 towards and treatments of, nociceptive,
6 neuropathic and mixed pain, right?

7 A. That's right.

8 Q. Did Janssen routinely engage
9 third parties to study and obtain
10 feedback from healthcare practitioners in
11 terms of the most compelling ways to
12 communicate efficacy, safety,
13 tolerability and mechanism of action
14 messages?

15 A. As a general concept,
16 getting the voice of the customer
17 typically entailed hiring a third-party
18 market research firm to engage outside
19 customers to understand their points of
20 view on a particular topic.

21 Q. And did Janssen routinely
22 engage third parties to go out and
23 perform market research to identify the
24 most clear and compelling ways to

1 communicate efficacy, safety,
2 tolerability and mechanism of action
3 messages?

4 A. Generally speaking, it was
5 very, very commonplace to use third
6 parties to -- third-party market research
7 experts to study things inclusive of the
8 things you've pointed out here.

9 So yes, this would be --
10 messaging would be one element of it.
11 And this is -- this is very commonplace
12 prior to a launch.

13 Q. Okay. For now I'm going to
14 put Exhibit 1 aside.

15 MR. JANUSH: I'm going to
16 mark as Exhibit 2, four documents
17 that I understand go together.
18 The Bates numbers -- I can pull
19 that for you. The Bates numbers
20 are JAN-MS-00131172, 131175,
21 131180, and 13155 for the record.

22 (Document marked for
23 identification as Exhibit
24 Janssen-Lin-2.)

1 BY MR. JANUSH:

2 Q. I'm presenting to you what's
3 been produced from the sales training
4 file share. So without getting into the
5 document and pausing for a moment, let's
6 talk about sales training file share.

7 Explain for us what the
8 sales training file share is.

9 A. Sir, I can't explain what
10 the sales training file share is.

11 Q. Are you familiar with the --
12 with the concept that there's a sales
13 training file share repository on your
14 network that sales representatives can
15 pull down training materials?

16 MR. GALIN: Objection to
17 form.

18 BY MR. JANUSH:

19 Q. Just asking.

20 A. I am aware that sales
21 training materials can be accessed by
22 sales reps.

23 The specifics of how it's
24 stored, how it's loaded, how it's

1 downloaded, how it's accessed is -- other
2 than someone gets it from their PC, I
3 could not speak intelligently to that.

4 Q. Okay. So these are videos
5 that were apparently produced in 2010
6 while you were the director of marketing
7 for the pain group. We're going to go to
8 the first page, Video 1, introduction
9 video. And it's a script, it appears,
10 from Frank DeMiro, product director for
11 Nucynta.

12 It starts by saying, "Hello
13 everyone, I'm Frank DeMiro, product
14 director for Nucynta. It is hard to
15 believe that we are well over six months
16 into the launch of Nucynta."

17 And this would be referring
18 to the launch of Nucynta IR, correct, in
19 2010?

20 A. That was the only product
21 that was approved at the time, so yes.

22 Q. Okay. And it states -- I'm
23 going to skip some of this. But, "You
24 have all worked extremely hard to raise

1 awareness of Nucynta and the dual
2 mechanism of action, not only with
3 physicians, but with pharmacists and
4 nurses too."

5 Do you see that?

6 A. Yes, I do.

7 Q. Okay. And I want to pause
8 here for a moment. Janssen never
9 actually established with clinical data,
10 approved by the FDA, that Nucynta has a
11 dual mechanism of action. Isn't that
12 right?

13 MR. GALIN: Objection to
14 form.

15 THE WITNESS: Mechanisms of
16 action are stated, or they are
17 described generally in a label.
18 But there's no -- there's --
19 mechanism of action is not
20 something that's ever studied in a
21 clinical trial for any drug.

22 MR. JANUSH: Move to strike,
23 nonresponsive.

24 BY MR. JANUSH:

1 Q. The label that was approved
2 by the FDA had a caveat concerning the
3 language of mechanism of action, didn't
4 it?

5 A. My recollection is yes.

6 Q. Do you remember what --
7 what's your recollection of what that
8 caveat was?

9 A. My recollection is that the
10 label would have said that the precise
11 mechanism of action is -- I'm not sure
12 what the word would be. But it's a
13 caveat to the point of --

14 Q. Unknown?

15 A. That might be it. Something
16 to the effect of unknown or not -- not
17 precise.

18 Q. And the only basis for
19 Janssen's dual mechanism of action
20 statements are derived from preclinical
21 rat studies, isn't that right?

22 A. My recollection of the basis
23 of this would be something other than
24 Phase III clinical trials. So I am

1 stating for the record, I don't know
2 whether it was preclinical, or if it was
3 a Phase I, but I believe it was not in
4 the Phase III pivotal trials that were
5 used for registration.

6 Q. And as you sit here today,
7 you don't -- you don't know one way or
8 the other whether it was only rat studies
9 through which the hypothesis of dual
10 mechanism of action was derived?

11 A. As I sit here before you
12 today, I want to reiterate for the record
13 that I came onto the brand in 2010 which
14 was following the launch of Nucynta. So
15 I was not involved and I am at the moment
16 unfamiliar with what constituted the
17 basis of some of those earlier statements
18 that were put into the label. It just
19 was before my time.

20 Q. Understood. But you were
21 also the director of marketing in 2010,
22 correct?

23 A. Correct.

24 Q. And so as the director of

1 marketing, the buck stops with you in
2 terms of marketing messages, I mean
3 you're the person most accountable for
4 marketing messages, right?

5 MR. GALIN: Objection to
6 form.

7 THE WITNESS: I am the
8 leader who makes a strong
9 recommendation on how the product
10 should be positioned, how it
11 should be messaged. And I do so
12 in consultation with the
13 appropriate legal, regulatory,
14 medical, healthcare compliance
15 checks.

16 BY MR. JANUSH:

17 Q. And in that role as director
18 of marketing, did you ever take the time
19 to review the label and the underlying
20 studies to make sure that when making
21 statements from a marketing perspective
22 about dual mechanism of action, that they
23 are -- those statements are supported by
24 science?

1 A. As the director of
2 marketing, my job is to make sure -- my
3 job at the time was to make sure that
4 everything we did regarding promotion of
5 the product was according to the label.

6 The specific underlying
7 studies that may have preceded me are
8 items that I would have absolutely leaned
9 on my medical and clinical colleagues for
10 historical perspective.

11 Q. And who would those
12 colleagues have been that you would have
13 leaned on for historical perspective?

14 A. Well, it would have been
15 people in the medical -- in the medical
16 affairs function. It could have been
17 colleagues from the R&D organization in
18 clinical affairs.

19 But I was not directly the
20 one verifying most of the things that we
21 are talking about.

22 Q. Well, Frank DeMiro worked
23 under you, right?

24 A. That's correct.

1 Q. And would Frank DeMiro have
2 verified his own statements independently
3 or -- I'm trying to get to the bottom of
4 statements like -- well, let's turn to
5 specifically the Video 4, which ends in
6 -- which is Bates Number 13115.

7 And I'm going to look at the
8 second bullet. I'm going to actually box
9 it in on this screen where it looks like
10 Frank DeMiro is saying, "Be sure to
11 always set up the dual mechanism of
12 action and include both the opioid and
13 nonopioid components.

14 "Our mechanism of action is
15 a key differentiating factor from other
16 currently available C-II opioids, so be
17 sure to speak specifically to the mu
18 opioid agonist and norepinephrine
19 reuptake inhibitor."

20 Do you see that?

21 A. Yes, I do.

22 Q. Do you agree with the
23 statement that your mechanism of action
24 regarding Nucynta was a key

1 differentiating factor from other
2 currently available C-II opioids?

3 A. I agree that at one point in
4 time it was believed to be a
5 differentiating factor based on what's
6 communicated here in the script.

7 Q. In 2010, do you know whether
8 the FDA would have allowed this
9 statement -- whether the FDA would have
10 viewed this statement to be in conformity
11 with the label?

12 MR. GALIN: Objection to
13 form.

14 THE WITNESS: So I'd like to
15 clarify. This appears to be
16 something that took place in 2010,
17 at the same time that I joined the
18 brand.

19 Anything that is produced
20 for sales training or promotional
21 communication with customers would
22 be reviewed by a cross-functional
23 team in the copy review process of
24 the organization, which would

1 comprise legal -- which would
2 comprise legal, medical,
3 regulatory, healthcare compliance,
4 and any other subject matter that
5 would have to weigh in as to its
6 accuracy. All materials at the
7 time of first use are in fact sent
8 to the FDA.

9 So I can't answer your
10 question specifically as to
11 whether the FDA would agree or
12 not.

13 What I can tell you is
14 everything that was done was
15 reviewed and sent to the FDA.

16 BY MR. JANUSH:

17 Q. You're not -- you're not
18 saying that script -- sales training
19 scripts and videos are sent to the FDA
20 for approval. You're not taking that
21 position, are you?

22 A. I'm just saying in general
23 everything is reviewed.

24 Q. When you say "everything," I

1 want to be -- break down what

2 "everything" means.

3 A. Okay.

4 Q. Because I think that --

5 that -- that you might -- you might be

6 going a little off the reservation in

7 terms of what the FDA reviews. So I'm

8 just trying to be careful here.

9 A. Okay.

10 Q. This is an internal video,

11 not an external piece that gets delivered

12 to a doctor as a leave-behind piece or a

13 product insert, a package insert.

14 This is a video script for

15 sales training purposes. Are you taking

16 the position that all of Janssen's video

17 scripts for sales training purposes got

18 reviewed by the FDA?

19 A. No, I'm not. I'm simply

20 saying that they are all reviewed

21 internally by a copy review committee.

22 Q. I understand that's your

23 position. You understand the

24 distinction, the fact that people might

1 review scripts internally doesn't
2 necessarily equate to accuracy? Do you
3 understand that as a concept?

4 MR. GALIN: Objection to
5 form.

6 BY MR. JANUSH:

7 Q. In other words, I'm
8 addressing -- I'm presenting you with
9 quotes from a video.

10 A. Yeah.

11 Q. And your answer is they
12 would have been reviewed internally.

13 I'm not asking you questions
14 about whether this would have been
15 reviewed internally.

16 I'm asking you questions
17 about whether you personally reviewed and
18 sought to ensure as director of
19 marketing, that statements -- sales
20 training scripts, were supported by the
21 package insert, were in conformity with
22 the package insert.

23 Do you understand what I'm
24 getting at?

1 A. Yeah, okay. So let me
2 clarify your question. You're asking me
3 if I personally verified the information
4 contained in the script?

5 Q. Right.

6 A. The answer is, I do not, I
7 did not personally verify all the
8 information that's contained in the
9 script.

10 Q. Next question. You had
11 addressed it's -- that the script would
12 be reviewed internally by a broad team of
13 others. How sure are you that sales
14 training videos would be reviewed by a
15 cross-functional team?

16 A. I would find it hard to
17 believe that anything like this would not
18 be. It was standard protocol that all
19 standard -- all sales training materials
20 would be reviewed by that promotional
21 review committee.

22 Q. Okay. So if there were --
23 was a mistake made, such that the
24 statements contained in the script are

1 deemed at a later date to have not been
2 in conformity with the label, that
3 mistake would, therefore, be owned by a
4 multitude of people?

5 MR. GALIN: Objection to
6 form.

7 THE WITNESS: I can't tell
8 you who owns the mistake.

9 If a -- if a mistake is
10 made, you're asking me to
11 conjecture as to where the
12 responsibility lies?

13 BY MR. JANUSH:

14 Q. Yes, I am.

15 A. I think the exact
16 responsibility -- the exact placement of
17 responsibility for a potential, and we're
18 talking about a hypothetical situation
19 right now, I don't know that I can answer
20 where that exact responsibility would sit
21 because it is through this process which
22 governs all of the materials that are
23 used, whether for sales training and/or
24 promotion.

1 (Document marked for
2 identification as Exhibit
3 Janssen-Lin-3.)

4 BY MR. JANUSH:

5 Q. I'm going to hand you what's
6 been marked as Lin Exhibit 3. This is --
7 does not have a Bates number on it. It's
8 the label -- we'll keep that out for a
9 minute. It's the label for Nucynta in
10 October 2010.

11 Turn to the page -- you can
12 feel free to find if it's anywhere else,
13 but turn to the page for mechanism of
14 action.

15 That mechanism of action
16 says, "Tapentadol is a centrally acting
17 synthetic analgesic. Although its exact
18 mechanism is unknown, analgesic efficacy
19 is thought to be due to mu opioid agonist
20 activity and the inhibition of
21 norepinephrine reuptake."

22 Do you see that?

23 A. Yes.

24 Q. So the FDA actually required

1 this language, "although the exact
2 mechanism is unknown."

3 Do you see that?

4 A. I do.

5 Q. And that's what you were
6 referring to earlier as being the caveat
7 language, right?

8 A. Yes.

9 Q. Are you aware that folks in
10 Janssen's medical liaison team would
11 correct others when -- when messages were
12 going out regarding the dual mechanism of
13 action and say, "You actually have to add
14 this language in, this label language,
15 'although the exact mechanism is
16 unknown'"? Have you ever seen that
17 happen?

18 MR. GALIN: Objection to
19 form.

20 THE WITNESS: Sir, I've
21 never seen that happen.

22 BY MR. JANUSH:

23 Q. Okay. Interestingly,
24 Kanitha Burns was one of your direct

1 reports?

2 A. She was.

3 Q. And I'm going to --

4 A. May I clarify? She was a
5 direct report to a direct report.

6 Q. Okay. And who was the
7 intermediary report?

8 A. Patricia Yap was the
9 intermediary.

10 Q. Okay. But going back to
11 this, you would agree that this is
12 limiting language that the FDA required
13 when speaking about mechanism of action,
14 correct?

15 MR. GALIN: Objection to
16 form.

17 THE WITNESS: I would agree
18 that it's a -- it's a
19 clarification that the exact
20 mechanism of action is unknown.

21 BY MR. JANUSH:

22 Q. So if the exact mechanism of
23 action is unknown, that renders it
24 difficult, if not impossible, to

1 unequivocally make statements about a
2 dual mechanism of action; isn't that
3 right?

4 A. If we are following the
5 label, I would agree with you that it
6 says it's unknown and it's thought. I'm
7 agreeing with the language.

8 Q. Right. So then going back
9 to the video script, if this was to be
10 tracking the label, wouldn't -- shouldn't
11 this have said, "Be sure to always set up
12 our thought that the dual mechanism of
13 action is due to mu opioid agonist
14 activity and the inhibition of
15 norepinephrine reuptake; however, the
16 exact mechanism of action is unknown."
17 That would be the most accurate way to
18 pitch to doctors mechanism of action
19 language when tracking the label, right?

20 MR. GALIN: Objection to
21 form.

22 THE WITNESS: I don't -- I
23 can't as -- let me be clear.

24 I am not a script writer for

1 sales training, nor am I a medical
2 expert who is really well versed
3 in the clinical attributes of this
4 molecule.

5 I agree with what the label
6 says. I cannot state for certain
7 what I think is the most accurate
8 way to portray it in a script.

9 BY MR. JANUSH:

10 Q. Let me say it differently.
11 FDA labels provide the ambit for what a
12 manufacturer of a drug can say about its
13 drug. True or false?

14 A. I believe the FDA -- the
15 United States package insert serves as
16 the home base of promotion.

17 Q. Will you at least be able to
18 admit that the statements contained in
19 this video nowhere address the qualifying
20 language that "the exact mechanism of
21 action is unknown"?

22 MR. GALIN: Objection to
23 form.

24 THE WITNESS: What we're

1 looking at here is a script for a
2 sales training video.

3 I acknowledge that the --
4 the words on this page are
5 different than the words contained
6 in the United States package
7 insert.

8 I cannot render an opinion
9 as to whether or not it's the best
10 representation of discussing the
11 mechanism of action in a sales
12 training video.

13 BY MR. JANUSH:

14 Q. I'd like to go back to --
15 I'm going to have you turn to a page in
16 the script at JAN-MS-00131177. I'm
17 putting it up on the screen so you can
18 see where I'm at.

19 MR. GALIN: Do you need
20 help?

21 THE WITNESS: Is that
22 Video 1, 2, 3 or 4?

23 BY MR. JANUSH:

24 Q. It's at Video 2, flashcard.

1 And this appears to be
2 addressing acute back and neck pain,
3 patients experience a variety of symptoms
4 and signs.

5 And next bullet is
6 addressing this mixture of symptoms and
7 signs have been associated with both
8 nociceptive and neuropathic pain
9 processes.

10 And here at the third bullet
11 it's addressing targeting both the
12 ascending and descending pathways may
13 provide more effective analgesia in
14 studies involving IV and epidural agents.

15 As you sit here today, do
16 you understand that that dual mechanism
17 of action involved a review of the
18 ascending and descending pathways, do
19 you -- do you recall that language at
20 Janssen?

21 A. Are you -- are you asking if
22 I've --

23 Q. If you --

24 A. -- if I've seen this

1 language before?

2 Q. Yeah. And specifically the
3 concept of ascending and descending
4 pathways.

5 A. I am familiar with the
6 concept, yes.

7 Q. Okay. What does it mean?

8 A. I think we've discussed the
9 mechanism of action and what is believed
10 to be working in two different parts of
11 the central nervous system.

12 Q. Okay. And interestingly in
13 this script, Janssen is addressing that
14 targeting both the ascending and
15 descending pathways, i.e., the dual
16 mechanism of action, may provide more
17 effective analgesia in studies involving
18 IV and epidural agents. Do you see that?

19 A. Yes.

20 Q. Nucynta was not an IV or
21 epidural agent, right?

22 A. That's right.

23 Q. So making a statement about
24 what is observed regarding descending

1 pathways when studying IV and epidural
2 agents doesn't have a bearing on Nucynta,
3 right?

4 MR. GALIN: Objection to
5 form.

6 THE WITNESS: I think it's
7 important that we're looking at an
8 entire video suite, which is, it's
9 context for training -- it's
10 context for training, so --

11 BY MR. JANUSH:

12 Q. Let me break that down.

13 A. Mm-hmm.

14 Q. Studies involving
15 the ascending and descending neuro
16 pathways concerning IV and epidural
17 agents, is context for Nucynta?

18 MR. GALIN: Objection to
19 form.

20 THE WITNESS: This is a --
21 let me clarify that this training
22 video script is -- I'm looking at
23 this for the first time.

24 I'm simply stating that in a

1 sales training video, there can
2 sometimes be references to other
3 components of science that are
4 irrelevant to the therapeutic area
5 in which your product is
6 competing.

7 I agree that that is not a
8 direct link -- it is not a
9 descriptor of Nucynta itself.

10 BY MR. JANUSH:

11 Q. And in fact, studies
12 regarding dual mechanism of action in IV
13 therapy or epidural agents were nowhere
14 addressed within the Nucynta label,
15 correct?

16 A. I can't verify or -- I can't
17 confirm or deny that.

18 Q. All right. Why don't you
19 take a look at Exhibit 3. Take as much
20 time as you need. And show me where dual
21 mechanism of action concerning IV or
22 epidural agents was deemed relevant to
23 the clinical pharmacology of Nucynta at
24 Page 15.

1 A. Could you ask your question
2 again after I've looked at this?

3 Q. Show me where the dual
4 mechanism of action concerning IV or
5 epidural agents was deemed relevant to
6 the clinical pharmacology of Nucynta.

7 A. So I don't see mention of IV
8 or epidural agents in this section.

9 Q. How about anywhere in the
10 label?

11 A. I'd have to read the label.
12 Would you -- would you like me to read
13 the label?

14 Q. Sure. I want to -- I want
15 to make sure that we are clear that
16 Janssen was using off-label scientific
17 discussions concerning IV therapy and
18 epidural agents to support a general
19 concept of a dual mechanism of action in
20 the context of promoting Nucynta.

21 MR. GALIN: Objection to
22 form.

23 BY MR. JANUSH:

24 Q. So I'd like you to review

1 the label and show me where there's any
2 support for this statement.

3 A. Okay. Could you just
4 clarify the question again, please?

5 Q. I asked you to review the
6 label.

7 A. Yes.

8 Q. And show me where there's
9 any support for the statement concerning
10 IV therapy and epidural agents to support
11 a general concept of dual mechanism of
12 action in the context of promoting
13 Nucynta.

14 A. After reviewing the label,
15 particularly the clinical pharmacology
16 section, which is where it would most
17 likely be stated, the words "regarding IV
18 and epidural" are not directly contained
19 within the label.

20 I'd like to clarify though,
21 that the context in the script was -- it
22 clearly referenced that those were -- the
23 mechanism of action and those agents were
24 separate and distinct, they made no

1 allusion to Nucynta.

2 Q. Isn't it true, however, that
3 this entire script is about Nucynta, and
4 supporting Nucynta's dual mechanism of
5 action is a component of this script?
6 You're not fussing on that point, right?

7 A. I haven't read the entire
8 script, sir. So I would agree there are
9 several parts of this. From what I see
10 as the -- after a quick scan, there
11 are -- show what there's -- there's
12 descriptors in the script about how to
13 use various pieces. There's also parts
14 in here that are meant to highlight,
15 through voiceover -- highlight specific
16 parts of their promotional pieces.

17 So, I don't have the full
18 context of what this script represented.
19 I'm only looking at copies here for the
20 first time.

21 Q. Okay. Well, can you turn to
22 the page where there's a picture of
23 the -- what looks like a sales rep/doctor
24 interaction. Its Bates number at the

1 bottom ends in 176.

2 A. Okay.

3 Q. "Rep script: Norepinephrine
4 place a critical role in pain
5 modulation."

6 Do you see that?

7 A. Yes.

8 Q. "The action of
9 norepinephrine in the descending pathway
10 modulates pain signals transmitted
11 through the ascending pathway."

12 Do you see that?

13 A. Yes.

14 Q. "Norepinephrine and mu
15 opioid receptors interact at multiple
16 levels in the central nervous system and
17 this interaction may help regulate pain
18 signals."

19 Did I read that right?

20 A. Yes.

21 Q. Okay. And that is
22 addressing the norepinephrine and the mu
23 opioid receptors, the dual mechanism of
24 action concerning Nucynta, right?

1 A. I agree with you that there
2 is reference to an ascending -- I'm
3 sorry -- a reference to --

4 Q. Descending?

5 A. -- descending and ascending
6 pathways.

7 There is not a mention of
8 Nucynta in that paragraph.

9 Q. Well, since we're going
10 to -- we're going to mince words like
11 that, why don't you skip to the bottom.
12 And I'm in the mentioning that there's a
13 Nucynta. I'm going to the closing
14 language that I'm boxing in here on the
15 screen.

16 "Doctor, would you agree
17 that the mechanism of norepinephrine
18 reuptake inhibition may be an important
19 part of your treatment plan for your pain
20 patients?"

21 This is clearly talking
22 about norepinephrine reuptake inhibition
23 in the context of a sales rep discussion
24 about Nucynta, isn't it?

1 MR. GALIN: Objection to
2 form.

3 THE WITNESS: This is what
4 would typically be construed as
5 an -- uncovering a physician need
6 and trying to acknowledge that
7 there could be room for something
8 that acted a little bit
9 differently, something new on the
10 market.

11 BY MR. JANUSH:

12 Q. Go back a page.

13 MR. JANUSH: I'm going to
14 move to strike that response as
15 nonresponsive.

16 BY MR. JANUSH:

17 Q. This is -- that page was the
18 second page. This is the first page.

19 "Video 2 flashcard." In the
20 middle of the page, "After addressing how
21 you will use the flashcard to communicate
22 key messages regarding the role of
23 norepinephrine and NRIs in analgesia."
24 It goes down to say, "Then you will

1 transition to the visual aid to review
2 the dual mechanism of action of Nucynta
3 as well as the clinical data and close
4 for the first choice use in moderate to
5 severe acute back and neck pain
6 patients."

7 Do you see that?

8 A. Yes.

9 Q. This is clearly addressing a
10 sales call, isn't it?

11 MR. GALIN: Objection to
12 form.

13 BY MR. JANUSH:

14 Q. In other words, it's a plan
15 for a Nucynta sales call. This is a
16 script for instructing a rep how to
17 transition to a visual aid to review the
18 dual mechanism of action of Nucynta,
19 isn't it?

20 MR. GALIN: Objection to
21 form.

22 THE WITNESS: The script as
23 I see it here, yes, is basically
24 saying use the flashcard, open the

1 call, and then transition to your
2 clinical message, which -- and
3 again I don't have the visual aid
4 in front of me. But if it's
5 saying here that the visual aid
6 contains the MOA and then the
7 clinical messages, then I think
8 what we're saying is yes, we would
9 want to have the flashcard precede
10 the visual aid in a sales call.

11 BY MR. JANUSH:

12 Q. And that this -- that the
13 discussion of mechanism of action and the
14 discussion of norepinephrine is in the
15 context of an overall conversation --
16 hypothetical conversation with a doctor
17 about Nucynta?

18 A. Yes.

19 Q. Okay. Thank you.

20 Now, earlier you said that
21 you didn't know whether the studies that
22 had been done concerning dual mechanism
23 of action were -- what did you say?
24 Phase III or what?

1 A. My comments were mechanism
2 of action, the supposed mechanism of
3 action, you asked me if these were only
4 studied through preclinical studies. I
5 responded I don't know exactly whether it
6 was preclinical or Phase I, because I
7 came in the market -- or I came onto the
8 brand, Nucynta was already launched. So
9 I couldn't be accurate as to exactly what
10 studies constituted that language in the
11 label.

12 Q. So let's clarify now.

13 A. Okay.

14 Q. Can you turn to Page 15 of
15 the label going back to clinical
16 pharmacology at Section 12.

17 A. Yes.

18 Q. All right.
19 Pharmacodynamics, do you see that?

20 A. Yes.

21 Q. All right. "Tapentadol is a
22 centrally acting synthetic analgesic. It
23 is 18 times less potent than morphine and
24 binding to the human mu opioid receptor

1 and two to three times less potent in
2 producing analgesia in animal models."

3 Do you see that?

4 A. Yes.

5 Q. The next sentence,

6 "Tapentadol has been shown to inhibit
7 norepinephrine reuptake in the brains of
8 rats, resulting in increased
9 norepinephrine concentrations."

10 Do you see that?

11 A. Yes.

12 Q. "In preclinical models" --
13 I'm circling that -- "the analgesic
14 activity due to the mu opioid receptor
15 agonist activity of tapentadol can be
16 antagonized by selective mu opioid
17 antagonists, whereas the norepinephrine
18 reuptake inhibition is sensitive to
19 norepinephrine modulators."

20 Did I read that right?

21 A. Yes.

22 Q. This is clearly only
23 limiting the dual mechanism of action to
24 preclinical rat studies, isn't it?

1 MR. GALIN: Objection to
2 form.

3 THE WITNESS: Yeah,
4 according to what's written here,
5 yes.

6 BY MR. JANUSH:

7 Q. Okay. That clarifies what
8 we were discussing earlier, right?

9 A. Yes.

10 Q. Okay. And indeed, the only
11 way to really test for mechanism of
12 action is to engage in post-label --
13 post-labeling tests that specifically
14 seek to test for mechanism of action and
15 prove that up with the FDA; isn't that
16 right?

17 MR. GALIN: Objection to
18 form.

19 THE WITNESS: I think that
20 would be -- it would be unfair for
21 me to comment on what studies
22 would be required to prove a
23 mechanism of action. That's a
24 clinical pharmacology job.

1 In my role as a brand
2 leader, I really wouldn't be able
3 to surmise what's the right
4 clinical studies to be done.

5 BY MR. JANUSH:

6 Q. Okay. So you just trusted
7 those around you that the statements
8 conveyed from your brand team were
9 correct?

10 A. There's a certain amount of
11 trust that you have to have in the
12 process to review what goes into things
13 like scripts, promotional materials, and
14 how you represent the brand.

15 We believed that there
16 was -- and I'm speaking during my time at
17 Janssen on the Nucynta brand. There's an
18 amount of faith you have to have in the
19 process, in the rigors of that process.

20 So to my earlier point about
21 I can't verify every single statement
22 that's made scientifically, you do have
23 to rely on the folks that are deemed to
24 be more expert.

1 Q. But this concept of a dual
2 mechanism of action was a key
3 differentiating factor to sell Nucynta as
4 being different than other opioids in the
5 class, wasn't it?

6 A. I can't -- I can state that
7 it was -- I can acknowledge that it was
8 in the video script that you showed me
9 here. And I can also state that during
10 my time on the brand, it was is deemed to
11 be not very effective in communicating
12 the efficacy and tolerability of Nucynta
13 in the eyes of prescribers.

14 MR. JANUSH: Move to strike.
15 Nonresponsive.

16 BY MR. JANUSH:

17 Q. I asked you whether it
18 was -- whether the concept of a dual
19 mechanism of action was a key
20 differentiating factor utilized by
21 Janssen to demonstrate when selling its
22 product, Nucynta, that it is different
23 from other opioids in the class. Is that
24 a true or false statement?

1 A. I can acknowledge that it
2 was part of the selling message. It was
3 a key communication point at one period
4 in time.

5 Q. And what period of time in
6 time was that?

7 A. My recollection is that was
8 at the early launch days of Nucynta and
9 shortly thereafter. One of my first
10 actions was that that was deemed to be
11 ineffective in terms of helping customers
12 really solve the problems they needed to
13 solve, which is does it work and can my
14 patients afford it.

15 Q. So when -- by the time that
16 Nucynta -- let's pin this down.

17 By the time that Nucynta ER
18 launched and you were the head of the
19 launch team, as well as the head of sales
20 and marketing and the head of the pain
21 force team, is it your testimony that
22 when ER launched, your brand team would
23 have stopped utilizing the dual mechanism
24 of action as a selling feature of Nucynta

1 ER?

2 A. Without the exact
3 promotional materials that were used at
4 the launch of Nucynta ER, I can't tell
5 you exactly how it was worded.

6 My recollection is, even if
7 it was mentioned as part of a broader set
8 of messages, it was only an
9 acknowledgment to the fact that it was
10 mentioned before, but it was not the key
11 selling feature of Nucynta ER.

12 Q. What, what became the key
13 selling feature of Nucynta ER?

14 A. My recollection, this is
15 strategically, is that the key messages
16 for differentiating Nucynta ER in the
17 eyes of customers, or in the minds of
18 customers, was really around its
19 efficacy, its tolerability.

20 So does it work was the
21 question that we tried to answer, because
22 that's the most common question asked by
23 physicians in my recollection of market
24 research.

1 Q. And how did you answer, as
2 head of the brand team, whether Nucynta
3 ER works?

4 MR. GALIN: Objection to
5 form.

6 THE WITNESS: I would go
7 right back to the promotional
8 message that was developed in
9 conjunction with our United States
10 package insert.

11 And we would go through the
12 clinical trial results, talking
13 about how Nucynta ER reduced pain
14 intensity in the model that was
15 studied.

16 We would then go into the
17 tolerability results of each of
18 those studies. And the overall --
19 the overall strategic intent was
20 to communicate that it does work.
21 And that's what formed the basis
22 of approval from the FDA.

23 BY MR. JANUSH:

24 Q. As you sit here today, do

1 you remember what the key messages were,
2 the core messages for Nucynta ER?

3 A. As I sit here today, and I'm
4 looking back many years now, efficacy,
5 tolerability, affordability, mechanism of
6 action could have been in there, but it
7 would have been not near the top of the
8 list. And that's strategically what I
9 would -- what I recall in terms of a core
10 message.

11 MR. GALIN: Mr. Janush, just
12 as a point of process --

13 MR. JANUSH: Yeah.

14 MR. GALIN: -- first, just
15 so those on the phone know, we're
16 writing down notes on -- using the
17 Elmo --

18 MR. JANUSH: You don't need
19 to interrupt my deposition to let
20 them know that we're writing
21 notes.

22 MR. GALIN: Well, I just
23 think they should know so that
24 they can follow along, since we're

1 seeing them here and they are not.

2 But what I do want to just
3 take a moment for, is it looks
4 like you're about to introduce a
5 new exhibit. We've been going for
6 a little more than an hour. I'd
7 be happy, if you think it's going
8 to be just a few more minutes and
9 the witness is okay going a little
10 longer, or would this be a good
11 time for a break?

12 MR. JANUSH: Good time for a
13 break.

14 THE VIDEOGRAPHER: Stand by
15 please. Remove your microphones.
16 The time is 11:09 a.m., going off
17 the record.

18 (Short break.)

19 THE VIDEOGRAPHER: The time
20 is 11:24 a.m. Back on the record.

21 (Document marked for
22 identification as Exhibit
23 Janssen-Lin-4.)

24 BY MR. JANUSH:

1 Q. Mr. Lin, I'm going to hand
2 you a document that I've marked as
3 Exhibit -- Lin Exhibit 4. Its Bates
4 stamp is JAN-MS-03007298. Its title is
5 "Common Objections and Appropriate
6 Responses." At the bottom of the page it
7 says, "For internal training use only."

8 Do you recognize this
9 document?

10 A. I can't speak to the exact
11 document, but I have seen documents that
12 do have things like common objections and
13 responses.

14 Q. Okay. So you've seen
15 documents of the type; is that right?

16 A. Yes.

17 Q. Okay. And this appears to
18 be a script to deal with objections and
19 appropriate responses when having a
20 conversation between a sales rep and a
21 doctor addressing at the top of the page
22 the differences between Nucynta and --
23 Nucynta IR and tramadol IR.

24 And -- is that right?

1 A. Yes.

2 Q. And then going more towards
3 the middle on the bottom of the page, it
4 seems to be an objection handler or
5 objection document with appropriate
6 responses for the sales rep to address a
7 doctor who is saying, "I will not use
8 Nucynta as a first choice agent."

9 Do I have that right?

10 A. Yes.

11 Q. Okay. Starting at the top,
12 the first bold heading. The topic is,
13 "What is the difference between Nucynta
14 IR and tramadol IR?"

15 Do you see that?

16 A. Yes.

17 Q. And it says, first answer,
18 "Doctor, there are many differences
19 between Nucynta and tramadol. For the
20 sake of this discussion, let's focus on
21 four of the differences."

22 And the first difference,
23 "Nucynta is a new molecule that is
24 unrelated to tramadol. Unlike tramadol

1 IR, Nucynta IR has a dual mechanism of
2 action which consists of mu opioid
3 receptor agonism and norepinephrine
4 inhibition reuptake."

5 Did I read that correctly?

6 A. Yes.

7 Q. Incidentally, is there any
8 qualifying language in this objection
9 handler document that addresses the exact
10 mechanism of action is actually unknown,
11 Doctor?

12 A. Well, based on the -- what's
13 written on the script, there's no other
14 language.

15 Q. Okay. So meaning there's no
16 other language other than an affirmative
17 statement that, unlike tramadol, Nucynta
18 IR has a dual mechanism of action; is
19 that right?

20 A. That's correct.

21 Q. Okay. Moving towards the
22 bottom. The third bullet to address the
23 objection handler -- well, actually,
24 earlier -- no, we'll stick with the third

1 bullet.

2 It says, "If the doctor is
3 not convinced of the differentiation
4 between Nucynta 50-milligram and
5 Oxycodone IR, go back and review the
6 ten-day end-stage joint disease pivotal
7 trial data regarding efficacy and the
8 improved GI tolerability."

9 Do you see that?

10 A. Yes.

11 Q. What was sought to be
12 conveyed regarding the ten-day end-stage
13 joint disease pivotal trial data? Do you
14 remember?

15 A. I know that -- I recall that
16 the end stage joint disease was one of
17 the key clinical trials highlighting in
18 the promotional message. But I can only
19 surmise from this training document that
20 it has -- there is compelling
21 differentiation in some measure of
22 tolerability.

23 Q. Between Nucynta and
24 Oxycodone IR, right?

1 A. No. Typically the studies
2 are not head-to-head. So they are
3 Nucynta immediate release in the same arm
4 versus placebo, and then an active
5 comparator versus placebo. So they would
6 be shown appropriately in that manner.

7 Q. So we agree with that
8 statement, that it's not a head-to-head
9 study, and that's how the data would be
10 shown. But I'm addressing the statement
11 made at Bullet 3. "If the doctor is not
12 convinced of the differentiation" -- that
13 means the difference, right -- "between
14 Nucynta 50-milligram and Oxycodone IR" --
15 let's just pause right there.

16 This opening to the bullet
17 is addressing making a differentiation
18 between Nucynta and Oxycodone IR,
19 correct?

20 A. Yeah, that's the -- that's
21 the preamble to the sentence.

22 Q. Right. Okay. "Go back and
23 re-review the ten-day end stage joint
24 disease pivotal trial data regarding

1 efficacy and the improved GI
2 tolerability."

3 The entire context is
4 addressing directing the rep to go back
5 and review the ten-day joint disease
6 pivotal trial data to continue to
7 differentiate between Nucynta and
8 oxycodone IR, right?

9 MR. GALIN: Objection to
10 form.

11 BY MR. JANUSH:

12 Q. I mean these -- these aren't
13 my words. I'm reading from a Janssen
14 script.

15 A. The -- the general approach
16 to differentiating a product in this
17 class or in any other class is to go back
18 to your clinical data, because that is
19 what's contained in your label and that's
20 usually the most compelling way to
21 convince a customer that there are some
22 differentiating features about your
23 product.

24 Q. Okay. I'm specifically

1 focusing on this language about
2 convincing a doctor regarding the
3 differentiation between Nucynta and
4 oxycodone IR. You with me?

5 A. I'm -- yeah, I'm tracking
6 with you.

7 Q. Okay. So tracking with me
8 on that notion --

9 A. Yes.

10 Q. -- that I'm specifically
11 focusing on the goal here, to
12 differentiate between Nucynta and
13 oxycodone IR, is to go back and re-review
14 the ten-day end stage joint disease
15 pivotal trial data regarding efficacy and
16 the improved GI tolerability.

17 Still tracking with me?

18 A. Yes.

19 Q. Okay. Do you remember what
20 the FDA said about the ten-day end stage
21 joint disease pivotal trial data and
22 whether Janssen was permitted to make
23 comparator statements between Nucynta and
24 oxycodone based on that data?

1 A. No, I don't.

2 Q. Did the -- would it concern
3 you if sales reps are being trained to go
4 back to a limited ten-day end stage joint
5 disease trial to make comparator
6 statements if the FDA deemed that trial
7 to be insufficiently numbered in terms of
8 its -- its depth and reach -- powered I
9 should say, that's the appropriate
10 word -- insufficiently powered to make
11 comparative statements?

12 Well, let's start with a
13 different premise. I'll strike that and
14 ask a different question.

15 Are you aware that the FDA
16 advised Janssen that the ten-day study
17 was insufficiently powered and not
18 appropriate -- not appropriately designed
19 with endpoints for Janssen to make the
20 statement that Nucynta had a better GI
21 tolerability profile as compared with
22 oxycodone?

23 A. No.

24 MR. GALIN: Objection to

1 form.

2 BY MR. JANUSH:

3 Q. You didn't know that?

4 A. I'm not aware of that.

5 Q. And if I'm right, and the
6 FDA advised Janssen that it could not
7 make such GI safety representations or
8 tolerability representations comparing
9 Nucynta to oxycodone, and that Janssen
10 was doing that, that would be a bad
11 thing, right?

12 MR. GALIN: Objection to
13 form.

14 BY MR. JANUSH:

15 Q. You can answer.

16 A. I think in general we -- we
17 would want to be sticking to the label,
18 and I would agree that we would want to
19 reference the right studies for the
20 right -- to -- to illustrate the right
21 point.

22 Q. Let's go back to that label
23 and -- do you have it, the exhibit? It
24 should be before you, the label?

1 Can you find support in the
2 label concerning this ten-day end stage
3 joint disease pivotal trial?

4 A. In 14.2, there is entry
5 called end stage degenerative joint
6 disease. Is that where we're -- that's
7 what I'm reading. There's 14.1, and
8 there's 14.2 under clinical trial.

9 Q. And in this end stage
10 degenerative joint disease portion of the
11 label, nowhere did the FDA permit Janssen
12 to include in its package insert a GI
13 comparison on improved tolerability as
14 compared with oxy, isn't that right?

15 MR. GALIN: Objection to
16 form.

17 BY MR. JANUSH:

18 Q. You can answer.

19 A. I'm just reading to make
20 sure that I understand the -- the
21 contents of the study here.

22 Q. In fact, and the reason you
23 won't find that is because this is a
24 different study than the ten-day study

1 that I was referring to. This study is
2 only studying Nucynta at 50 milligrams
3 and 75 milligrams with a placebo. This
4 is not the ten-day joint study that I was
5 referring to concerning oxycodone as a
6 comparator in the class. Do you
7 understand that?

8 A. I under --

9 Q. So the point I'm trying to
10 make is, if this is the only study you're
11 able to point to addressing a -- a joint
12 disease study, and it's not the oxycodone
13 study, it inherently means that the FDA
14 didn't permit Janssen to include an
15 oxycodone comparator ten-day study in the
16 label with the statement that there is an
17 improved GI tolerability presented by
18 Nucynta as compared with oxy. Do you
19 understand me?

20 MR. GALIN: Objection to
21 form.

22 BY MR. JANUSH:

23 Q. I'll try and clean it up.
24 I'm trying to get the concept out.

1 In other words, earlier you
2 said you had tracked to the label, you'd
3 looked to the label to see what you could
4 say, right?

5 A. Yes.

6 Q. And I'm asking you to look
7 to the label and find anything on an oxy
8 comparison where Nucynta and its ten-day
9 end stage joint disease pivotal trial
10 data was permitted by the FDA to be
11 included in -- in the label to address
12 Nucynta's improved GI tolerability over
13 oxy. And I don't think it can be found.
14 I want to know if you agree.

15 MR. GALIN: Objection to
16 form.

17 THE WITNESS: I acknowledge
18 that the version of the label that
19 I'm looking here, the version I'm
20 looking at here, this label from
21 2009, in the clinical trial
22 section, I see two studies. One
23 is an orthopedic study. And the
24 other one is entitled -- sorry.

1 End Stage Degenerative Joint
2 Disease.

3 I'm still trying to
4 reconcile -- I'm just trying to
5 reconcile your question of -- that
6 these are different studies.

7 It's been a long time since
8 I've --

9 BY MR. JANUSH:

10 Q. Well, the way I can give you
11 that comfort I think is -- and I'm not --
12 I'm not trying to testify. I'm trying to
13 be accurate with you.

14 Because when you turn to
15 Page 21 and you look at Figure 2?

16 A. Okay.

17 Q. And the measurements are
18 charted. The package insert is comparing
19 placebo to Nucynta 50-milligram and
20 Nucynta 75-milligram at Day 5, do you see
21 that?

22 A. Yes.

23 Q. And oxycodone is missing
24 from the grid, right, from the chart?

1 A. Yes, that's right.

2 Q. And if you go back a page to
3 the start and the explanation of the
4 study, it says, "A randomized
5 double-blind parallel group active and
6 placebo-controlled multiple-dose
7 study" -- multiple dose study, I'm boxing
8 that in -- "evaluated the efficacy and
9 safety of 50-milligram and 75-milligram
10 Nucynta given every four to six hours
11 during waking hours for ten days in
12 patients aged 18 to 80 years."

13 Do you see that?

14 A. Yes.

15 Q. Nothing about this study is
16 about oxy -- has to do with oxycodone,
17 right?

18 A. I -- I can't say that for
19 certain. Because the word active -- I
20 acknowledge that there's Nucynta 50 and
21 75 and I acknowledge there's placebo, but
22 there's -- what I'm trying to recollect
23 is when it says active, that might be an
24 active comparator.

1 Q. Okay.

2 A. So --

3 Q. And if it was, and if I'm
4 wrong, and it -- and this is the ten-day
5 joint disease study and it included oxy
6 as an active comparator, the FDA
7 certainly didn't permit a comparison
8 statement to be made in this package
9 insert that there was improved GI
10 tolerability for Nucynta IR as compared
11 with oxy, true or false?

12 MR. GALIN: Objection to
13 form.

14 BY MR. JANUSH:

15 Q. It's not in here, right?

16 A. There -- there is no word
17 regarding oxycodone here in the
18 description of the study.

19 I am alluding to that it
20 possibly could be, because it says active
21 control which often is referencing
22 there's another compound being tested
23 against placebo.

24 To answer the question

1 about -- I want to go back and say the
2 context. If this was a sales training
3 document, these are not actual claims.
4 They -- we'd have to look in totality,
5 which is look at the actual visual aid
6 and what's portrayed that. Because that
7 would, in fact, be the -- to triangulate
8 what was the actual message that was
9 delivered to a customer.

10 MR. JANUSH: Move to strike,
11 nonresponsive.

12 BY MR. JANUSH:

13 Q. We're on this document, the
14 package insert, the label. And I had a
15 question pending.

16 A. I agree with you that the --
17 as currently stated in the label, there
18 is no direct reference in 14.2 to the
19 word oxycodone.

20 Q. Or to the notion that the
21 active comparator was -- had a worse GI
22 safety profile than Nucynta, right?

23 A. That is not stated in 14.2.

24 Q. And again, just to recap,

1 you were unaware that the FDA had advised
2 Janssen it could not make comparator
3 representations regarding improved GI
4 tolerability of Nucynta over oxycodone,
5 correct?

6 A. That's correct. I'm not
7 aware.

8 (Document marked for
9 identification as Exhibit
10 Janssen-Lin-5.)

11 BY MR. JANUSH:

12 Q. I'm going to move on to
13 Exhibit Number 5, which is Bates-marked
14 JAN-MS-01122345.

15 MR. JANUSH: I'm going to
16 hand a copy to counsel and another
17 copy to counsel. Did I hand you
18 the actual exhibit? Let me swap
19 with you.

20 MR. GALIN: Do you want the
21 exhibit back?

22 MR. JANUSH: Nope.

23 BY MR. JANUSH:

24 Q. All right. This is an

1 e-mail string. And it starts with an
2 e-mail from Nanette Meyer on the third
3 page.

4 Do you see that at the
5 bottom?

6 A. Yes.

7 Q. And you are listed as a
8 recipient. I'm circling it so you can
9 see where it is on the screen and find
10 it. And it's January 5th, 2012. And
11 it's addressing a -- what's called a
12 warning letter regarding statements about
13 Nucynta. And I'm going to turn to the
14 last page specifically.

15 It says, "In a warning
16 letter, the division of drug marketing,
17 advertising, and communications said it
18 has become aware of oral statements made
19 by an Ortho-McNeil Janssen representative
20 on January" -- "on December 8, 2010, at
21 the 2010 American Society of Health
22 System Pharmacists Midyear Clinical
23 Meeting and Exhibition in Anaheim,
24 California, regarding its drug Nucynta,

1 immediate release oral tablets, C-II.

2 "The representative's
3 statements promote an unapproved use for
4 Nucynta, make unsubstantial superiority
5 and other claims about the drug and
6 minimize the serious risks associated
7 with Nucynta."

8 Do you see that?

9 A. Yes.

10 Q. Do you remember receiving
11 this e-mail and learning about the FDA's
12 letter to Janssen in 2012 concerning a
13 2010 promotion -- speech given by a rep
14 at this American Society of Health System
15 Pharmacists Midyear Clinical Meeting?

16 A. I cannot recall the exact
17 instance of receiving this e-mail. I
18 would typically be made aware of things
19 like this, so it is perfectly within my
20 day-to-day life that I would have learned
21 of it, but I don't -- I don't recall this
22 exact correspondence.

23 Q. Okay. Without addressing
24 whether you recall the exact e-mail

1 itself, do you recall the subject matter
2 that I'm addressing, because it's not
3 every day that the FDA issues a letter
4 concerning false promotional statements
5 about a drug, right?

6 MR. GALIN: Objection to
7 form.

8 THE WITNESS: I don't -- I
9 can't speak to how often FDA makes
10 corrections on people's -- on our
11 promotional messages.

12 This particular instance --
13 BY MR. JANUSH:

14 Q. We'll get into it more. I'm
15 going to get into detail. I'm not trying
16 to play hide-the-ball.

17 A. Okay.

18 Q. I'm just trying to ask
19 you -- I'm actually serious about
20 establishing the concept that it isn't an
21 everyday or every week occurrence that a
22 manufacturer gets a letter from DDMAC
23 contending that a sales representative
24 went off-label and made statements that

1 are unapproved? I'm right about that,
2 right?

3 A. I would agree that it's not
4 a very common occurrence.

5 Q. Okay, thanks.

6 (Document marked for
7 identification as Exhibit
8 Janssen-Lin-6.)

9 BY MR. JANUSH:

10 Q. I'm going to hand you what
11 I've marked as Exhibit 6. It's Bates
12 number JAN-0003-0002930. I'll hand you
13 that.

14 MR. JANUSH: And give a copy
15 to your counsel.

16 BY MR. JANUSH:

17 Q. And turning to the first
18 page, this is a letter that was
19 transmitted to Roxanne McGregor-Beck,
20 associate director of regulatory,
21 advertising and promotion.

22 Do you see that?

23 A. Yes.

24 Q. Did you interface with

1 Roxanne Beck in your role as leading the
2 marketing team?

3 A. Yeah. She was the
4 regulatory leader for Nucynta.

5 Q. And actually, in 2012 --
6 let's see. The interesting thing here is
7 that that e-mail string that I addressed
8 earlier at the prior exhibit was
9 addressing, in 2012, in January of 2012,
10 a letter that seems to have been
11 transmitted on August 26, 2011.

12 In fact, on the prior
13 exhibit, just so that we're clear, it
14 says that in the second portion of the
15 e-mail string on the first page, "Chris,
16 attached please find the letter we
17 received from DDMAC back in August of
18 2011 in regard to an interaction that
19 they had with a sales representative at a
20 medical convention."

21 Do you see that?

22 A. Yes.

23 Q. And I'm only doing that and
24 circling back to make it clear to you

1 that when I'm presenting you with this
2 August 26, 2011, fax cover sheet and
3 accompanying letter, that we are on the
4 same page that it is the letter that's
5 referenced in the e-mail here, okay?

6 A. I -- okay.

7 Q. I'm going to give you a
8 moment to review this letter, because I
9 want to know whether it's your position
10 that you recall receiving this important
11 letter from DDMAC.

12 Now, realistically, I should
13 swap with you, because I marked up the
14 wrong copy that I put a sticker on. So
15 we'll just re-sticker this. I didn't do
16 much with it, but I put two highlights on
17 it. So I'm going to draw your attention
18 to those sections any way.

19 I see that you finished
20 reading the document, right?

21 A. Yes.

22 Q. Okay. There's -- there's at
23 least three things that I'd like to -- to
24 address with you for this document.

1 Number one, I'd like to
2 address the topic with you concerning the
3 fact that statements were made off-label
4 that diabetic peripheral neuropathy
5 patients, or DNP patients could stay on
6 Nucynta longer, and that Nucynta provides
7 10 milligrams of opioid oxycodone pain
8 control, similar to tramadol, but with
9 less GI constipation, nausea and
10 vomiting.

11 That's Topic 1, okay?

12 Topic 2 is that I'm going to
13 address with you the GI safety
14 comparisons that are addressed within
15 this letter concerning Nucynta having a
16 better GI safety profile than oxycodone
17 and tramadol. Okay?

18 And Topic 3 is -- concerns
19 the notion that Nucynta has been shown to
20 release hospital stays in comparison to
21 oxycodone and tramadol. You with me
22 still?

23 A. Yes.

24 Q. And --

1 MR. GALIN: Objection to
2 form.

3 BY MR. JANUSH:

4 Q. And I may add a fourth
5 topic, but I just wanted to outline for
6 you where I'm going so that it's going to
7 be easy to follow me. And if you don't
8 understand something that I'm addressing,
9 just let me know.

10 So turning to Page 2. At
11 the bottom of the page there's a
12 subheading, Unsubstantiated Superiority
13 Claims/Minimization of Risk.

14 Do you see that?

15 A. Yes.

16 Q. It says, "During the
17 December 8, 2010, discussion at ASHP, the
18 Ortho-McNeil Janssen representative
19 further indicated that DPNP patients stay
20 on Nucynta for longer and Nucynta
21 provides 10 milligrams of opioid
22 oxycodone pain control, similar to
23 tramadol, but with less GI constipation,
24 nausea and vomiting."

1 Now, my question for you is,
2 is this claim misleading because it
3 implies that Nucynta is clinically
4 superior, i.e., safer, as compared to
5 oxycodone and tramadol for DPNP patients?

6 A. I think there's a lot of
7 parts to that question. So there's no
8 indication -- Nucynta did not have an
9 indication, to the best of my knowledge,
10 still does not have an indication,
11 Nucynta immediate release, for the relief
12 of pain associated with diabetic
13 peripheral neuropathy, so --

14 Q. So as a threshold matter, it
15 was off-label to address diabetic
16 peripheral neuropathy?

17 A. Yes.

18 Q. Okay. We agree.

19 Now, addressing the next
20 component which is that the claim
21 misleadingly implies that Nucynta is
22 safer as compared to oxycodone and
23 tramadol, isn't that correct?

24 MR. GALIN: Objection to

1 form.

2 BY MR. JANUSH:

3 Q. The -- the claim
4 misleadingly implies clinical
5 superiority, i.e., safety, compared to
6 oxycodone and tramadol?

7 MR. GALIN: Objection to
8 form.

9 THE WITNESS: I agree with
10 the statement as written in the
11 letter.

12 BY MR. JANUSH:

13 Q. Okay. So what I'm -- what
14 I'm -- what I was about to say is, my
15 question isn't being plucked from thin
16 air. It's actually tracking the language
17 of the FDA's reprimand, right?

18 A. I think that the statement
19 as written here is how I would construe
20 that finding for sure.

21 Q. And the statement is this
22 claim misleadingly implies that Nucynta
23 is clinically superior, i.e., safer,
24 compared to oxycodone and tramadol for

1 DPNP patients, right?

2 A. I think the claim is
3 incorrect, yeah.

4 Q. And then the second
5 sentence, the ensuing sentence states,
6 "Specifically, it," meaning the claim,
7 "implies that Nucynta has been shown to
8 have less GI gastrointestinal adverse
9 reactions, i.e., constipation, nausea,
10 and vomiting, in comparison to oxycodone
11 and/or tramadol when this is not the
12 case."

13 Do you see that?

14 A. Yes.

15 Q. So this isn't just saying
16 the statement is wrong in the context of
17 diabetic peripheral neuropathy. The FDA
18 at that sentence is saying the statement
19 of comparison regarding GI issues, that
20 Nucynta is better than oxy and/or
21 tramadol, that's just not the case
22 generally, isn't that right?

23 A. If the claim that was made
24 is what's highlighted here in the bullet

1 point, then I -- I would agree that those
2 claims are -- if that -- if that, in
3 fact, is the claim that the FDA is
4 offering, commenting about, which it is
5 here, then those -- that superior safety
6 or superior -- or a comparison to
7 oxycodone or tramadol, is, in fact,
8 incorrect.

9 Q. Okay. And then it goes on
10 to say, "We note that although safety
11 data was collected from patients taking
12 Nucynta and oxycodone during the clinical
13 studies for Nucynta, FDA determined that
14 the studies were not adequately powered
15 for the analysis of multiple safety
16 endpoints, and that the dose of oxycodone
17 used as a comparator was not demonstrated
18 to be equianalgesic to the doses of
19 Nucynta studies."

20 Do you see that?

21 A. Yes.

22 Q. And that means like not
23 equal to the doses of Nucynta studied,
24 right, that word, equianalgesic?

1 A. The word generally in this
2 category means if you take X milligrams
3 of one drug that's -- there's not enough
4 evidence necessarily to say that it's
5 equal to a particular milligram of
6 another drug.

7 Q. And the FDA goes on to say,
8 "Therefore, safety comparative data were
9 not considered clinically meaningful and
10 were not included in the approved PI for
11 Nucynta."

12 Do you see that?

13 A. Yes.

14 Q. Earlier we -- we went
15 through this, and I know I'm going to be
16 introducing this later document to you,
17 we went through this with the label and I
18 was addressing where the safety
19 comparison was for Nucynta to be deemed
20 improved or better than oxy. Do you
21 remember that?

22 A. Yes.

23 Q. And it was lacking, right?

24 A. That's correct.

1 Q. And now, you're seeing that
2 it was lacking because the FDA didn't
3 permit Janssen to make statements that
4 Nucynta had a better GI safety profile as
5 compared with oxycodone, right?

6 MR. GALIN: Objection to
7 form.

8 THE WITNESS: Yeah, I'm --
9 I'm acknowledging that what you've
10 just said is what's contained in
11 this letter. Yeah.

12 BY MR. JANUSH:

13 Q. And you don't disagree with
14 this history, right?

15 As you sit here today,
16 you're reading an FDA letter --

17 A. Yeah.

18 Q. -- you have nothing to say
19 the FDA got it wrong and what we're
20 addressing here is incorrect?

21 MR. GALIN: Objection to
22 form.

23 THE WITNESS: There are --
24 I'm acknowledging that this letter

1 is very clear about what the
2 finding was at this particular
3 event.

4 What I can't state for
5 certain, because I just simply
6 have no firm recollection, is
7 there are multiple interactions
8 with FDA ongoing around clinical
9 studies, interpretation of
10 studies.

11 But, yeah, in the instance
12 that we are talking about here,
13 it's right there.

14 BY MR. JANUSH:

15 Q. And the instance we are
16 talking about here is not limited to
17 necessarily -- it's calling out a
18 speaking event that occurred in -- in
19 2010, but it's a 2011 letter addressing
20 the limitations within Nucynta's label,
21 isn't it?

22 MR. GALIN: Objection to
23 form.

24 THE WITNESS: Let me make

1 sure I understand --

2 BY MR. JANUSH:

3 Q. Meaning, meaning, it's
4 addressing the concept that although
5 safety data was collected from patients
6 taking Nucynta and oxycodone during the
7 clinical studies for Nucynta, FDA
8 determined that the studies were not
9 adequately powered for the analysis of
10 multiple safety endpoints and that the
11 dose of oxycodone used as a comparator
12 was not demonstrated to be equal to the
13 doses of Nucynta studied.

14 Did I read that right?

15 A. You did.

16 Q. That's not limited to just
17 the representatives statement in 2010 at
18 a convention. That's a sweeping
19 statement about the clinical study
20 presented for the labeling of Nucynta,
21 isn't it?

22 A. I'd agree that reflects what
23 their opinion of the label is at that
24 point in time.

1 Q. Okay.

2 A. Yeah.

3 Q. Okay. And moving further,
4 "In addition" -- middle of the page --
5 "during the December 8, 2010 discussion
6 at ASHP, the Ortho-McNeil Janssen
7 representative indicated that when
8 physicians prescribe Nucynta, they:
9 'Won't have to put patients on docusate
10 or senna. Patients get out of the
11 hospital a day earlier, which saves
12 thousands of dollars because they're
13 going to be able to have a bowel
14 movement.'"

15 Did I read that right?

16 A. Yes.

17 Q. And the FDA came back and
18 said, "This claim mistakenly implies that
19 treatment with Nucynta has been shown to
20 reduce length of hospital stay in
21 comparison to oxycodone and tramadol."

22 Did I read that correctly?

23 A. Yep.

24 MR. GALIN: Actually, I

1 think you mistakenly said

2 "mistakenly" instead of

3 "misleadingly."

4 MR. JANUSH: Misleadingly.

5 Sorry. My eyes are playing tricks

6 on me.

7 BY MR. JANUSH:

8 Q. And then at the bottom of

9 the paragraph, I'm going to skip down to

10 the sentence beginning with "in

11 addition," and I'm highlighting so you

12 can follow me.

13 "In addition, as detailed

14 above, the lack of support for comparing

15 the safety and efficacy of Nucynta to

16 oxycodone and tramadol makes it

17 impossible to make a treatment cost

18 comparison based on the length of

19 hospital stay. If you have any evidence

20 to support such claims, please submit it

21 to FDA for review."

22 Do you know whether, after

23 receiving this letter, Janssen ever

24 submitted to FDA for review any support

1 for the notion that being on Nucynta
2 would reduce the length of a hospital
3 stay due to less constipation as compared
4 to other Schedule II opioid products?

5 A. I'm not aware of what
6 follow-up correspondence took place as it
7 relates to that element of the letter or
8 any other parts of the letter.

9 Q. Now, moving on to the
10 section entitled "Unsubstantiated
11 Efficacy Claim."

12 "The sales representatives
13 statement that Nucynta provides
14 10-milligram of opioid oxycodone pain
15 control similar to tramadol is misleading
16 because it implies that Nucynta has been
17 shown to be non-inferior to oxycodone,
18 tramadol, or other opioids.

19 "Specifically, the claim
20 implies that Nucynta has been shown to
21 provide equivalent pain control,
22 equianalgesia, when compared to other
23 opioids, including oxycodone and
24 tramadol.

1 "We note that although
2 oxycodone was included as an active
3 comparator in the arm" -- "active
4 comparator arm in the clinical studies
5 for Nucynta, FDA determined that your
6 analyses to obtain a non-inferior claim
7 regarding the efficacy of Nucynta
8 compared to oxycodone were inadequate,
9 and the results of those analyses were,
10 therefore, excluded from the approved
11 PI."

12 Do you see that?

13 A. Yes.

14 Q. The FDA then goes on to say.
15 "The FDA is not aware of any well
16 controlled head-to-head clinical trials
17 comparing the efficacy of Nucynta to
18 tramadol or any other opioids."

19 And it asks, "If you have
20 any evidence to support this claim,
21 please submit it to FDA for review."

22 Do you know if any evidence
23 was supported -- was submitted to support
24 this claim --

1 A. I don't know the status --

2 Q. -- after receiving this
3 letter?

4 A. I don't know the status of
5 any follow-up correspondence with the FDA
6 on any of these matters.

7 Q. What's your understanding of
8 the concept of off-label marketing,
9 generally?

10 A. That's a pretty broad
11 question. I would say generally
12 speaking, if you're representing the
13 product outside of indication, or
14 anything that's not substantiated by the
15 evidence that you have in the label, that
16 would generally be recalled -- generally
17 be referred to as off-label.

18 Q. And is off-label marketing
19 permitted or impermitted --
20 impermissible?

21 A. Off-label marketing is
22 absolutely not permitted.

23 Q. So it's improper to market
24 off-label messages about Nucynta to a

1 doctor, right?

2 A. It is improper.

3 Q. And as shown in this
4 instance, it's a pretty big deal for a
5 sales representative -- well, let me --
6 let me ask a different question.

7 The letter that we were
8 addressing from the FDA concerned a
9 Janssen sales representative that was
10 speaking at a pharmaceutical conference,
11 right, in Anaheim?

12 A. I'm looking back at the
13 exhibit.

14 Q. The American Society of
15 Health System Pharmacists Midyear
16 Clinical Meeting and Exhibition.

17 A. It definitely appears that
18 it was a sales representative. I can't
19 tell from the e-mail or the letter what
20 was the context in which they were
21 speaking, meaning was it a large
22 audience, was it a one-on-one. If your
23 question was to elaborate on that, I'm
24 sorry, I misunderstood.

1 Q. What I'm addressing is a
2 sales representative was employed by
3 Janssen and was representing the company
4 at the American Society of Health System
5 Pharmacists Midyear Clinical Meeting and
6 Exhibition, right?

7 A. Yes, it appears that way.

8 Q. And the sales representative
9 that Janssen had permitted to attend this
10 meeting made unsubstantiated statements
11 about the superior GI tolerability
12 compared to other opioids, right?

13 MR. GALIN: Objection to
14 form.

15 THE WITNESS: I acknowledge
16 that the sales rep was mentioned
17 here in this letter to have made
18 those comments.

19 BY MR. JANUSH:

20 Q. So at least as of the date
21 of this letter from the FDA in August of
22 2011, the FDA was conveying to Janssen
23 that Janssen and its sales reps were not
24 permitted to market the concept that

1 Nucynta had a superior GI tolerability as
2 compared to oxycodone; isn't that right?

3 A. That's my interpretation,
4 yes.

5 Q. Okay. So that was August of
6 2011, that FDA letter. And now I'm going
7 to take you forward to a 42-slide
8 PowerPoint called "Unleashing the Power,"
9 where the document metadata for this
10 PowerPoint shows that it was 12/6/2011,
11 so about four months later following the
12 FDA letter.

13 (Document marked for
14 identification as Exhibit
15 Janssen-Lin-7.)

16 BY MR. JANUSH:

17 Q. And I'm producing to you
18 JAN-MS-0114237 as Exhibit Number 7.

19 And the custodian for this
20 PowerPoint is a gentleman that you
21 mentioned earlier named Dominic Lazzaro.
22 And if we go to the Page 2 of this
23 PowerPoint, Mr. Lazzaro is right here.
24 You're at the top. Going to the left

1 side it looks like, Mr. Lazzaro was under
2 Lisa -- how do I pronounce her last name.
3 Bianciani or Bianciani?

4 A. I don't know. I think it's
5 Lisa Bianciani.

6 Q. Bianciani. And Lisa appears
7 to be, although not directly under
8 Kanitha Burns, perhaps all of these are
9 direct -- Kanitha Burns, Lisa, and
10 Dominic Lazzaro all appear to be direct
11 reports to Tricia Yap; is that right?

12 A. Yeah, that's how it should
13 appear.

14 Q. And Tricia Yap is a direct
15 report to you; is that right?

16 A. Yes.

17 Q. Okay. And it's addressing
18 at Page 2, "This is our brand team.
19 David Lin is our fearless leader and our
20 director of marketing. Tricia Yap has
21 recently joined our team, coming over
22 from Ethicon, and is our group product
23 director."

24 Dominic Lazzaro is tasked

1 with below, "Detail strategy and NP/PA
2 strategy, as well as speaker programs and
3 medical meetings, retail Puerto Rico."

4 What is -- digital strategy
5 refers to digital marketing strategy; is
6 that right?

7 A. Yes, generally.

8 Q. Okay. And what's NP/PA
9 strategy? Is that focusing on nurse
10 practitioners and physician assistants?

11 A. Yes.

12 Q. And tell us about what it
13 means to be responsible for speaker
14 programs and medical meetings.

15 A. Speaker programs were an
16 important part of the educational
17 component of -- of brand, particularly at
18 launch.

19 So in the instance of
20 Nucynta, a speaker program would have
21 been otherwise known as a speaker bureau.
22 There's a core content of information
23 about the product. There are some number
24 of key faculty that are trained to

1 deliver them -- the message. And then
2 those faculty would conduct speaker
3 programs in various locations around the
4 country, usually anywhere from -- it's
5 hard to generalize, but I would say ten
6 to fifteen people in a venue. And they
7 would deliver that promotional message.

8 Q. Okay. And incidentally, you
9 had corrected me earlier when I had only
10 addressed that you were director of
11 marketing. You said director of sales
12 and marketing.

13 At this time, this should
14 have been listed director of sales and
15 marketing as well, if this is truly from
16 December 6, 2011, because, as we went
17 over your resumé or your history of
18 employment, you were director of sales
19 and marketing at that time, right?

20 A. No. I was director of sales
21 and marketing starting December of 2012
22 going into 2013.

23 Q. Got it.

24 A. That was -- that was the

1 time that we made that change.

2 Q. I'll cross that out.

3 And incidentally, when you
4 moved over to director of sales and
5 marketing, did all of these people stay
6 under you?

7 A. I would say some did. Some
8 moved on to new assignments. They're --
9 these teams are living, breathing, so
10 it's -- my recollection is that one or
11 two of them moved on to different
12 assignments by 2013.

13 Q. And who may they have been?
14 You still worked with Tricia
15 Yap, right?

16 A. If I'm thinking back to
17 2013, Tricia Yap was on the brand. Frank
18 DeMiro. Ron Kuntz. Kanitha Burns. And
19 I believe by that time Lisa Ferguson had
20 moved on to another role. And I also
21 believe that Lisa Bianciani -- I believe
22 she moved during that time, but I can't
23 be certain of the date.

24 Q. I'd like to go back to

1 Page 1 of this PowerPoint. And let's
2 talk about the image of the lion and the
3 rose unleashing the power. Somewhere in
4 this document or another document, I read
5 about the fact that this lion was
6 actually a real lion from the San Diego
7 Zoo. I think counsel is laughing
8 at this.

9 This was -- this was to
10 convey -- it's at Page 11. The lion
11 in -- in the picture was a real lion from
12 the San Diego Zoo named Major, and
13 Janssen is saying he's symbolic to the
14 brand because a lion is big and
15 powerful -- big and powerful, yet he's
16 able to hold a rose which shows the
17 gentle nature.

18 Do you see that?

19 A. Yes, I see that.

20 Q. Were you part of approving
21 this brand marketing campaign of a lion
22 with a rose in his mouth to convey that
23 Nucynta is strong but gentle?

24 A. I was definitely part of

1 approving the use of this icon.

2 Q. Okay. And the concept was
3 to convey efficacy and tolerability,
4 right?

5 A. Among many factors, that was
6 one of the factors.

7 Q. And it was the factor that
8 was highlighted in Mr. Lazzaro's
9 presentation, wasn't it?

10 A. It was -- I'd like to
11 clarify. These are speaker notes. They
12 don't necessarily mean that they were
13 ever spoken.

14 These are -- speaker notes
15 during -- during these kinds of
16 presentations are often used by speakers
17 only to get a sense of how they'd like to
18 communicate.

19 It doesn't necessarily mean
20 that they were actually the one that
21 communicated it and it -- because I don't
22 know what was the ultimate version that
23 was used on stage.

24 So I think for clarity, I'd

1 just like to offer up that speaker notes
2 are often your best thinking at the time
3 that the slides are constructed. They
4 don't necessarily mean that they were the
5 ones spoken. And the words that were
6 chosen for the notes were not always the
7 ones that were used on stage.

8 Q. Understood.

9 MR. JANUSH: Move to strike,
10 nonresponsive. I didn't have a
11 question pending on that topic.

12 BY MR. JANUSH:

13 Q. We'll move over to Slide 9.
14 And we'll focus on the slide.

15 And this presentation is
16 addressing Nucynta total prescriptions,
17 that's what TRx stands for, right?

18 A. Yes.

19 Q. Is highly concentrated. Is
20 this intended to be -- be --
21 approximately 7,000 targets make up
22 approximately 80 percent of the business?

23 A. Yes.

24 Q. Then there's a chart, a pie

1 chart, and it's showing active writers
2 versus nonactive targets.

3 And this seems to be
4 indicating that your active Nucynta
5 writers comprise 28 percent of total
6 targets as of this point in time; is that
7 right?

8 A. Yes, that's my takeaway.

9 Q. Okay. And when we -- when
10 we speak about targets, you're utilizing
11 underlying data to figure out who your
12 prescriber targets are. And I don't know
13 how good your eyes are, but looks to be
14 that there's a source reference down here
15 that says IMS Xponent, GPharma WE. And
16 it looks like it says September 16, 2011.

17 Do you see that?

18 A. Yes.

19 Q. So that means that you --
20 you have gotten your data on these
21 Nucynta prescribers from IMS Xponent
22 data; is that right?

23 A. Yes.

24 Q. Okay. And here --

1 MR. GALIN: Which slide did
2 you go to?

3 MR. JANUSH: Slide 12.

4 MR. GALIN: Thank you.

5 MR. JANUSH: Sure.

6 BY MR. JANUSH:

7 Q. At Slide 12, the
8 presentation is addressing data to
9 compete with OxyContin. Do you see that?

10 A. Yes.

11 Q. This refers to the chronic
12 low back pain study, the diabetic
13 peripheral neuropathy pain study, the DPN
14 study, and the one year safety study,
15 right?

16 A. Yes.

17 Q. And do you know whether
18 the -- do you know what -- what the
19 outcomes were concerning the chronic low
20 back pain study as it concerned Nucynta
21 versus placebo with an OxyContin active
22 control?

23 A. Are you asking if I recall
24 the exact --

1 Q. Yeah, do you recall what the
2 results were, you know, broadly speaking?

3 A. Broadly speaking, if we
4 were -- if we were using these studies as
5 the basis of promotion, then the finding
6 would typically be that we'd see Nucynta
7 ER versus placebo as being highly
8 effective. We would also see OxyContin
9 as the active control also being
10 effective. And you would see Nucynta ER
11 versus placebo in tolerability also being
12 effective. And the same with OxyContin,
13 generally speaking.

14 Q. Let's break that answer down
15 a bit.

16 Earlier in your testimony
17 today and right now, you acknowledged the
18 notion that OxyContin was an active
19 control, right?

20 A. Active comparator.

21 Q. Active comparator.

22 Was this a head-to-head
23 study with OxyContin?

24 A. No.

1 Q. No. And because it wasn't a
2 head-to-head study, that limits the
3 ability to make certain representations
4 about the outcomes of the study results
5 as it concerns Nucynta being more
6 tolerable or having less GI adverse
7 events as compared with oxycodone; isn't
8 that right?

9 A. I think it would be fair to
10 say you couldn't say it in the way you've
11 just stated it.

12 Q. Okay. So you could say it
13 in a wordsmithy way but not in the way I
14 said it?

15 A. You can --

16 MR. GALIN: Objection to
17 form.

18 THE WITNESS: The way you
19 can do it in pharmaceutical
20 promotions is to show both arms of
21 the study and let the data be
22 representative of the data.

23 BY MR. JANUSH:

24 Q. In other words, you can show

1 a chart, but you can't talk about it?

2 MR. GALIN: Objection to
3 form.

4 THE WITNESS: You can still
5 talk about it. And there's
6 appropriate words that were placed
7 on any -- on any visual aid or
8 training document that would
9 acknowledge, here's how you talk
10 about it.

11 BY MR. JANUSH:

12 Q. What would be an example of
13 appropriate words as to how you would be
14 able to talk about Nucynta ER having a
15 better GI safety profile as compared with
16 the active control of OxyContin?

17 MR. GALIN: Objection to
18 form.

19 THE WITNESS: I think -- I
20 think that's a -- I've been away
21 from this category for a very long
22 time, so I think it would be
23 inappropriate for me to respond to
24 or to conjecture about what's

1 appropriate when I'm not actively
2 involved in the business.

3 BY MR. JANUSH:

4 Q. So moving to Page 19 or
5 Slide 19. Here is a chart that is
6 addressing powerful efficacy.

7 Do you see that?

8 A. Yes.

9 Q. And in the text it's saying,
10 "You'll also want to highlight the study
11 design on this asset by pointing out the
12 doses studied, placebo, Nucynta ER
13 100-milligram to 250 milligrams and
14 OxyContin 20 milligrams to 50 milligrams.
15 This will be important later when we
16 discuss dosing. Remember, it was a not a
17 head-to-head study and oxycodone CR was
18 included as an active analgesia control
19 for assay sensitivity. Nucynta's ER pain
20 reduction from baseline here is both
21 statistically and clinically
22 significant," right?

23 That's what it says right?

24 A. That's what it says, yes.

1 Q. Okay. Do you know whether
2 these words got conveyed at the
3 conference, at the meeting?

4 MR. GALIN: Objection to
5 form.

6 BY MR. JANUSH:

7 Q. No?

8 A. You're asking me to comment
9 as to whether these -- whether these
10 precise words were communicated at a
11 meeting that we haven't discussed?

12 Q. Well, this is -- this was a
13 meeting addressing the launch of Nucynta
14 ER, right?

15 A. Will you remind me of the
16 date stamp of this file?

17 Q. Actually I'm wrong. I
18 apologize. This is a meeting discussing
19 Nucynta ER generally and progress made.
20 I believe this was December 6, 2011. Was
21 it the launch? Let's see. I have two
22 different PowerPoints. I want to make
23 sure I'm not confused either.

24 I think this was the meeting

1 addressing the launch of "Unleashing the
2 Power," the new branding campaign
3 regarding the lion with the rose -- with
4 the rose in its mouth.

5 With that said, that's not
6 so important. So I'm going to move on.
7 Earlier, I was addressing the comparator
8 issues and GI-related adverse events. So
9 I'm going to direct your attention to
10 Page 21.

11 And the notes are addressing
12 the top -- the chart at the top
13 concerning gastrointestinal disorders
14 reported in at least 5 percent of
15 patients at any treatment group, placebo,
16 Nucynta ER, and oxycodone ER.

17 Do you see that? Do you see
18 that?

19 A. Yes, yes.

20 Q. And at the bottom the notes
21 say, "You'll see the system organ class
22 results pop up as a bar graph, showing
23 the GI-related adverse events for
24 placebo, Nucynta ER and OxyContin. Like

1 we always say, a picture is worth a
2 thousand words. Be sure to stay
3 disciplined with your message here and
4 don't make comparative statements."

5 Do you see that?

6 A. Yes.

7 Q. Earlier I said you're not
8 allowed to make comparative statements,
9 and you said something to the effect --
10 and I don't want to paraphrase -- that
11 certain statements could be made
12 consistent with the data.

13 So I want to understand. Do
14 you agree that you can't make comparative
15 statements concerning the outcome of this
16 study?

17 A. Yes.

18 Q. You agree with that?

19 A. Yes.

20 Q. Okay. So if that was done
21 following the chronic lower back pain
22 study and sales reps were trained to make
23 comparison statements between Nucynta ER
24 and OxyContin, that would be a bad thing,

1 right?

2 A. That would be inconsistent
3 with the direction they'd been given.

4 Q. When you say "they were
5 given," you're not, as you sit here
6 today, making a generalization, are you,
7 that sales and marketing folks never gave
8 scripts or PowerPoint presentations to
9 sales reps to address the comparison
10 between OxyContin and Nucynta's GI safety
11 profile, are you?

12 MR. GALIN: Objection to
13 form.

14 BY MR. JANUSH:

15 Q. You're not taking the
16 position that that never happened, are
17 you?

18 A. I'm taking the position that
19 as a brand leader, working in partnership
20 with my colleagues in sales, we would
21 never have made a -- given sales
22 direction or any materials or produced
23 any materials that would have done as
24 you've described.

1 MR. JANUSH: Off the record.

2 THE VIDEOGRAPHER: The time
3 is 12:36 p.m. Going off the
4 record.

5 - - -

6 (Lunch break.)

7 - - -

8 A F T E R N O O N S E S S I O N

9 - - -

10 THE VIDEOGRAPHER: We are
11 back on the record. The time is
12 1:42 p.m.

13 - - -

14 EXAMINATION (Cont'd.)

15 - - -

16 BY MR. JANUSH:

17 Q. Mr. Lin, I'm going to
18 transition into a different topic and I'm
19 going to address, in as general a manner
20 as I can, budget concerns or budget
21 information with respect to the Nucynta
22 brand, okay.

23 As the marketing leader of
24 Nucynta for a period of time, and as the

1 sales and marketing leader for Nucynta
2 thereafter, did you have occasion to
3 review Janssen's Nucynta budgets, annual
4 budgets?

5 A. If you're speaking about the
6 annual marketing budget, for sure, yes.

7 Q. Yes. Okay. Would you
8 typically get those in an Excel file, for
9 example?

10 A. They are constructed using
11 Excel typically. And they can be
12 presented either in Excel, sometimes a
13 PowerPoint, sometimes a Word document.
14 It all depends on the exact view that the
15 audience is looking for.

16 Q. Do you have a facility with
17 receiving Excel file and filtering it and
18 drilling down for your group when seeking
19 to review an annual marketing budget?

20 A. I'm not sure I understand
21 the question.

22 Q. Do you know how to use
23 Excel?

24 A. Yes, I do.

1 Q. Okay. Are you proficient
2 with it?

3 A. Yes, I am.

4 Q. You know how to filter for
5 data and determine exactly what you want
6 to find in a given marketing plan?

7 A. I know -- I'm familiar with
8 how to use filters. I never had occasion
9 to use filters or sort data in a way that
10 you're describing, not with Nucynta.

11 Q. I'm not talking about
12 complex pivot tables --

13 A. Yeah.

14 Q. -- but generally, do you
15 know how to -- like if you wanted to look
16 at the budget for Kanitha Burns, would
17 you have known, sitting in your office at
18 Janssen, how to click on a person and see
19 what, what are they responsible for as an
20 example?

21 MR. GALIN: Objection to
22 form.

23 THE WITNESS: If a budget --
24 I think the more accurate way for

1 me to describe it is a budget is
2 made up of different categories
3 and there's different line items.
4 Not typically are they formally
5 associated with a person.

6 BY MR. JANUSH:

7 Q. I'm going to start with a
8 presentation, PowerPoint slides, that
9 concerns, I believe, 2010 and 2011 budget
10 figures. It may also include 2009 budget
11 figures. And it addresses a concept of
12 2010 OE-PBP BME's total Nucynta. Do you
13 have any idea of what OE-PBP BME's means?

14 A. My recollection is that OE
15 stands for October estimate. PBP would
16 stand for preliminary business plan.

17 So my -- my recollection
18 would be that would be a snapshot in time
19 that represents sometime in the October
20 time frame --

21 Q. Got it.

22 A. -- previewing the year --
23 the year later.

24 Q. So for example, and -- and

1 I'll produce this to you for review in a
2 minute. I just want to learn a little
3 more before I start asking questions in
4 greater detail.

5 If I'm looking at 2010
6 OE-PBP and the chart breaks down 2009
7 ACT, that means actual, right?

8 A. Yes. ACT would mean actual.

9 Q. And then 2010 OE is an
10 October estimate for 2010, meaning we're
11 in -- we're in month 10 of 12, this is
12 what we estimate for the rest -- for
13 2010?

14 A. Yes. That's generally where
15 do you think the spend would be --

16 Q. In the next two months?

17 A. -- in that year.

18 Q. Total --

19 A. Total for the year.

20 Q. The only -- the only months
21 you're estimating at that point are the
22 remaining two, correct? Meaning purchase
23 orders get filled, invoices get paid if
24 it's October?

1 A. I just -- no, the October
2 estimate designation is just a rough
3 point in time. So the October estimate
4 could probably mean any time from
5 September to the end of the year --

6 Q. Okay.

7 A. -- up until you actually
8 have an actual.

9 Q. And then the 2011 PBP, what
10 would that stand for again?

11 A. That would be the
12 preliminary business plan for what you
13 think the budget might be. Well, that's
14 what you're work -- that's the assumption
15 you're working on for the following year.

16 Q. Okay. So I'm going to
17 produce to you what we're marking as
18 Exhibit 8.

19 (Document marked for
20 identification as Exhibit
21 Janssen-Lin-8.)

22 BY MR. JANUSH:

23 Q. I'm going to have you help
24 me -- walk me through it. It's a --

1 marked JAN 008227. I'll move the clip.

2 It's a draft of the 2011 business plan?

3 And just turn to Page 4 if
4 you will. And Page 4 isn't necessarily
5 looking at budget issues. It's looking
6 at key issues and strategies; is that
7 right?

8 A. That's correct.

9 Q. And so specifically it's
10 addressing that skeptical and habitual
11 marketplace, what would that mean?

12 A. As described here, it's a --
13 it's just a generalization of the
14 environment in which this product is
15 competing. That is to say, very loosely,
16 because, you know, again I don't -- I
17 don't have the exact context of the time.
18 This -- the Schedule II opioid market,
19 which is the, in this case it would be
20 short-acting opioids, it's a -- we
21 described it as a skeptical market
22 because there is a lot of entrenchment,
23 so there's not a lot of new agents. And
24 so we had, at the time, a dominant player

1 in oxycodone, most of which was generic.
2 And what's described as habitual
3 marketplace is that not unlike a lot of
4 other categories, once physicians become
5 used to writing a particular product for
6 a particular condition or a patient type,
7 it's really hard for them to adopt
8 something new. So, it's generally just
9 saying it's a tough market.

10 Q. And one of the things that
11 made it tough was the other side of this
12 chart, it says, "Nucynta not viewed as
13 superior to oxy molecule."

14 And would you agree with
15 that, with that statement, as a business
16 key issue and key strategic issue that
17 you were facing?

18 A. Yes. And it was absolutely
19 an issue that was highlighted.

20 Q. Okay. And let's talk about
21 growth strategies.

22 Strengthen differentiation
23 through new and compelling evidence.
24 What was the goal here?

1 A. The goal basically is to
2 differentiate the product versus what's
3 existing in the market. And at its most
4 basic level, create some sort of
5 awareness with the prescribing audiences,
6 and in so doing, get them to try the
7 product.

8 Q. And moving over to drive
9 favorable and competitive access --

10 A. Yes.

11 Q. -- what's that referring to?

12 A. The -- the concept of market
13 access relates to the payer environment.
14 So the majority -- I shouldn't
15 mischaracterize majority.

16 The -- the basic payment
17 channels in the United States are private
18 insurance, Medicare, Medicaid, those are
19 the major players. And when you're a new
20 product to launch, it was incumbent upon
21 the brand to -- to gain access and not be
22 disadvantaged in the eyes of the doctor
23 and the patient.

24 Specifically, we're saying

1 as favorable and competitive means let's
2 get on a level playing field so that
3 there's not a reason to deny writing the
4 product because of cost only.

5 Q. So was there an effort
6 within Janssen to get Nucynta on as many
7 formularies as is possible?

8 A. Generally speaking, there
9 was an effort for the targeted channels
10 to make sure that the access was as much
11 on par with the competitors as possible.

12 Q. What is this -- what do you
13 mean by targeted channels?

14 A. Let's say we're targeting
15 private insurance, Aetna, CIGNA, you want
16 to be -- you -- you have to look at each
17 channel or each plan in and of itself.
18 So if a product, let's say that's already
19 been in the market is Tier 1, generics
20 are typically Tier 1, so there's either
21 free or maybe \$5 for a co-pay. You want
22 to be as high up on the tiers as makes
23 sense for the brand, so that it doesn't
24 look like the out-of-pocket is extremely

1 high and cost prohibitive for a patient.

2 Q. And as a branded product
3 that was new to the market, it had a
4 price premium over a generic, Nucynta
5 did, right?

6 A. Yes, it did.

7 Q. And that made it a little
8 harder for Janssen to compete in the
9 market; is that right?

10 A. Being new and being at a
11 higher price point would be a challenge
12 in the beginning.

13 Q. So tell the Court in this
14 case, what Janssen did in order to gain
15 better market access?

16 A. The principle means to get
17 better access would basically be to
18 negotiate a more favorable rebate to
19 payers where we thought the business
20 would be most relevant.

21 Q. Can you explain that in
22 greater detail?

23 A. So generally speaking,
24 there's a list price. And most

1 manufacturers will discount off that list
2 price, thereby reducing the co-pay to the
3 patient. And so you -- a brand would
4 seek to offer a rebate that would allow
5 it to be competitive with the other
6 agents in the class. The exact
7 competitive mix is going to differ by
8 plan, but to try to put -- to put the
9 brand in a competitive position that was
10 less disadvantaged from a cost
11 perspective to the patient.

12 Q. Now, there's two different
13 types of rebates, as I understand it, at
14 least. There's the rebate that you're
15 speaking about with regard to a seller or
16 a distributor selling your drugs, getting
17 a discount off list price, right?

18 A. I'm sorry. You've mentioned
19 distributors.

20 Q. A seller of Nucynta getting
21 a discount off list price?

22 MR. GALIN: Objection to
23 form.

24 THE WITNESS: I'm not

1 tracking, when you say a seller of
2 Nucynta. Do you mean the actual
3 company, Janssen?

4 BY MR. JANUSH:

5 Q. No. Janssen sells it --
6 sells Nucynta through distribution
7 channels, right?

8 A. That was -- yes, that was
9 the primary means.

10 Q. Okay. So who is getting the
11 rebate?

12 A. The rebate that I'm speaking
13 about is to the health plan.

14 Q. Okay. So there's a health
15 plan rebate. Do you know anything about
16 the subject of chargebacks?

17 A. Broadly speaking --

18 Q. Let's first start with
19 defining what it is. What's a
20 chargeback?

21 A. I'm not sure I can give a
22 precise answer to a chargeback. I can
23 speak to the fact that if there was a
24 Medicaid rebate, Medicaid would settle up

1 with the manufacturer at the quarter's
2 end, and there would typically be a
3 chargeback of some sort. That's an
4 example.

5 Q. And that's when, for
6 example, the price paid for the drug is
7 less than the price -- the price
8 ultimately paid for the drug is less than
9 the sale price was to the initial buyer,
10 correct?

11 MR. GALIN: Objection to
12 form.

13 THE WITNESS: I can't speak
14 to whether -- it was -- when you
15 say the --

16 BY MR. JANUSH:

17 Q. In other words, if you're
18 selling a drug to Medicaid, but Medicaid
19 gets paid less than the list price, than
20 some differential, constitutes a
21 chargeback, and a rebate back to -- and
22 Medicaid is probably not the best
23 example.

24 A better example would be if

1 you're selling a drug to McKesson, as an
2 example, and McKesson is paying a
3 contract price with Janssen. Isn't it
4 the case that when they represent that
5 they failed to sell the drug at that
6 contract price, they seek a chargeback?

7 MR. GALIN: Objection to
8 form.

9 THE WITNESS: I can't speak
10 to that. I don't have --

11 BY MR. JANUSH:

12 Q. So you don't have knowledge
13 on that?

14 A. I don't have enough
15 experience.

16 Q. Fair enough. I'm going to
17 move on to a different topic. Next
18 topic.

19 You talked about -- you
20 talked about rebates generally. Your
21 marketing group created a coupon program
22 for Nucynta.

23 Do you remember that?

24 A. I recall there was a patient

1 assistance program that was created. But
2 the exact name, I can't recall right now.

3 Q. Okay. Leave the exact name
4 aside. Why don't you tell us everything
5 that you can about that coupon program?

6 A. My recollection is with
7 Nucynta, there were some -- there was a
8 program that offices could hand to
9 patients that allowed them to get some
10 number -- some portion of their
11 prescription at a discounted rate when
12 they go to pharmacy.

13 Q. And that was to assist
14 patients in getting their first
15 prescription, right?

16 A. That was the intent, yes.

17 Q. And the concept is that once
18 patients have their first prescription
19 and like the drug, hopefully they'll stay
20 on the drug, right?

21 MR. GALIN: Objection to
22 form.

23 THE WITNESS: The -- I can't
24 characterize it as that.

1 The program, in my
2 recollection, it was for Nucynta
3 immediate release which had,
4 according to the indication, a set
5 amount of time.

6 The rationale for
7 implementing that program was that
8 coverage with managed care was not
9 very strong. And the
10 out-of-pocket cost would have been
11 very prohibitive for most patients
12 to even afford that one
13 prescription.

14 So, hence, in order to help
15 to allow offices to get some
16 patients started, they were given
17 an allotment of these -- I think
18 they were called co-pay cards, to
19 help certain patients get started.

20 BY MR. JANUSH:

21 Q. Do you remember hiring
22 McKesson to administer a co-pay program
23 with Janssen on Nucynta?

24 MR. GALIN: Objection to

1 form.

2 THE WITNESS: I don't recall
3 who -- I don't recall which
4 company we selected to administer
5 that program. If you are -- if
6 you're asking if McKesson could
7 have been one of them, it would
8 have had to have been one of the
9 larger distributors that provided
10 that type of service.

11 BY MR. JANUSH:

12 Q. Do you recall how much money
13 was charged by that third party to
14 administer the rebate program?

15 A. I do not.

16 Q. Does \$2 million plus ring a
17 bell to you?

18 A. I can't put \$2 million in
19 context of total cost of --

20 Q. Well, we'll work with
21 something later and see what we can do.

22 I'm going to have you turn
23 to Page 15 of this exhibit. And at Page
24 15 am I correct that this is addressing

1 the October review of 2010 with a
2 business plan forecasting for a total
3 budget of \$44 million for 2011; is that
4 right?

5 A. Yeah, that looks like this
6 is what this is trying to depict.

7 Q. Okay. And in 2010, the
8 October analysis of the 2010 budget shows
9 a total budget projection for Nucynta
10 marketing at \$36 million; is that right?

11 A. Yes.

12 Q. With 21 percent of that
13 broken down to agency. What does agency
14 mean? Is that advertising agencies?

15 A. That is usually encompassing
16 an advertising agency. It could also
17 entail media buying agencies. But
18 broadly speaking, third-party outside
19 agency.

20 Q. Okay. And it shows that
21 21 percent of the budget is dedicated to
22 speaker programs.

23 And can you describe what
24 that's referring to, speaker programs?

1 A. Here, based on my
2 recollection of the program, was the
3 brand had a speaker bureau, which was a
4 collection of -- it was a trained group
5 of doctors and possibly nurse
6 practitioners, who could speak -- who
7 were trained to speak about the brand,
8 according to the promotional program and
9 the promotional content. And they would
10 be invited to speak to doctors in the
11 community based on a program that our
12 representatives set up with that
13 doctor -- with that speaker.

14 Q. Okay. So 21 percent of
15 \$36 million total budget equates to, by
16 my rough math, somewhere just a tick
17 above \$7.2 million dedicated to speaker
18 programs. That's a lot of money to
19 devote to paying for programs to have
20 doctors go out and speak with other
21 doctors, isn't it?

22 A. Launching a new product,
23 sir, requires some resources.

24 Q. And the coupons and vouchers

1 is estimated at 10 percent of the total
2 budget, so \$3.6 million. Fair to say
3 that's right?

4 A. Yes.

5 Q. Okay. And that's addressing
6 \$3.6 million of total budget that's spent
7 on making it easier for patients to
8 access that, at least, the first
9 prescription; is that right?

10 A. For Nucynta, yes, the
11 program is designed to help reduce the
12 upfront cost for a prescription.

13 Q. And I see 16 percent in
14 purple dedicated to sales force support.
15 What kind of sales force support would be
16 included in a budget like this?

17 A. For sales force support,
18 it -- I'm just wanting to be cognizant of
19 the other buckets. So here this is
20 probably the materials, the actual -- the
21 cost of producing actual physical
22 materials that a sales force would use.

23 So it could be the
24 promotional visual aid that's on their

1 iPad. It could be flashcards. It could
2 be publications. It could simply be
3 reprinting of a package insert that's
4 required to be left behind on every call.

5 Q. Does it include the sales
6 force overhead?

7 A. No. Nothing in these
8 budgets would be --

9 Q. Personnel?

10 A. -- would touch personnel.

11 Q. And when we look to 2011,
12 the budget was projected to increase by
13 \$8 million; is that right?

14 A. That is the number being
15 proposed on that particular day. I can't
16 speak to whether that was the final
17 number.

18 Q. Understood. Do you recall
19 why the budget needed to -- or why there
20 was a proposal to increase the budget by
21 \$8 million? Would it have been tied to
22 the notion of Nucynta ER's launch?

23 A. The -- I can't -- I can't
24 recollect exactly what the rationale was

1 for going up. The increase in overall
2 spend typically would have to do with,
3 I'm looking at the -- the categories, the
4 percentage -- the percentages didn't
5 change, but the absolute amount might
6 have gone up in correlation with an
7 expected rise in forecast.

8 Q. Well, the percentage has
9 changed a bit. For example, speaker
10 programs went from 21 percent to
11 24 percent. Agency fees appeared to go
12 down a bit. But let's talk about that,
13 that speaker program issue once more.

14 Do speaker programs include
15 both advisory board meetings as well as
16 key opinion leader-led discussions?

17 A. The speaker program -- the
18 speaker programs, as I understand these
19 classifications, would be the latter of
20 what you said, which is just speaker
21 programs.

22 Q. So hiring a key opinion
23 leader to present on pain-related issues
24 to other physicians.

1 A. I just want to clarify. The
2 people that spoke on behalf of the brand
3 were known as the speaker bureau. Those
4 were all folks that were trained. So,
5 yes, if -- if you mean hiring a -- or
6 putting someone on a contract to be part
7 of the bureau to deliver promotional
8 talks, that's absolutely included in the
9 speaker bureau.

10 Q. And internally at Janssen
11 you referred to these folks as key
12 opinion leaders, didn't you?

13 A. Well, the term can be
14 interchangeable. Sometimes folks would
15 call them key opinion leaders.
16 Oftentimes just a speaker in the speaker
17 bureau.

18 Q. I'd like to move to page --
19 I think it's 29, but the page numbers are
20 listed vertically. It ends in Bates
21 number 8255. Do you see that?

22 A. Yes.

23 Q. Okay. So here, when we are
24 talking about 2009, in 2010 it's listed

1 as ACT. That's actual, right?

2 A. Yes.

3 Q. So for 2009, Janssen spent
4 \$39.2 million to market Nucynta IR and
5 \$1.5 actual million to market ER, for a
6 total of \$40.6 million; is that right?

7 A. That's correct what's on the
8 page.

9 Q. Okay. And moving to the
10 next page. We are addressing the
11 breakdown by color coding for the
12 strategy for 2011 spend by strategy,
13 total Nucynta.

14 And here it says total
15 budget, 44 million. And the green
16 represents the largest amount,
17 26.4 million allocated toward accelerate
18 trial and adoption. What does that mean?

19 A. If we are talking about
20 Nucynta, total Nucynta, most of the
21 business plans were categorized or broken
22 up into just general -- general
23 categories to give you a sense of how --
24 how an investment was being directed.

1 So accelerating trial and
2 adoption was just another way to cut all
3 the different line items that are in a
4 longer Excel spreadsheet. So this would
5 include something like the agency costs,
6 because the agency's work is to help
7 develop the messages that are used to
8 promote the product. So that would be
9 typically included in something like
10 accelerate trial and adoption.

11 Q. Would it include making
12 Janssen's contribution payment to pain
13 advocacy groups?

14 A. I can't speak based on
15 what's here, whether that would include
16 making a sponsorship to an advocacy
17 group.

18 Q. While you were running the
19 Nucynta marketing brand, incidentally,
20 did you have involvement in who Janssen
21 would work with, with regard to promoting
22 pain management through pain advocacy
23 groups?

24 MR. GALIN: Objection to

1 form.

2 THE WITNESS: As a head of
3 the brand, one of the things that
4 I was charged to do was making
5 overall resource allocation, as we
6 saw from the percentages.

7 So generally my role
8 entailed, is one area of
9 investment overweighted versus
10 another, and trying to find the
11 optimal mix.

12 In that mix is a small
13 amount, relative to the larger
14 total, for sponsorships and
15 participation or engagement with
16 advocacy organizations.

17 BY MR. JANUSH:

18 Q. Which groups do you recall
19 engaging with, which advocacy
20 organizations?

21 A. Well, I'd have to be clear,
22 the engagement with advocacy
23 organizations were done through a
24 advocacy director, who --

1 Q. Who is that?

2 A. The person that -- that I'm
3 most familiar with, in terms of handling
4 advocacy was Robyn Kohn who was the
5 national advocacy director for internal
6 medicine.

7 Q. Is it Cohen, C-O-H-E-N,
8 or --

9 A. K-O-H-N. And it's Robyn
10 with a Y.

11 Q. And that title is national
12 advocacy director?

13 A. That's my recollection of
14 her title.

15 Q. Okay. And tell us about
16 what Robyn Kohn would do, what was her
17 function in terms of engaging with
18 advocacy groups?

19 A. My recollection is that
20 Robyn interfaced with -- across
21 therapeutic areas for Janssen internal
22 medicine, and was the interface to any
23 advocacy organization. So beyond that, I
24 couldn't tell you how the day-to-day role

1 was handled, I was not in day-to-day
2 conversations in that area. Because I
3 was responsible for bigger -- a bigger
4 set of the responsibilities of the brand.

5 Q. What involvement, if at all,
6 did you have in interfacing with pain
7 management advocacy organizations, for
8 example like AAPM?

9 A. My only involvement as it
10 relates to advocacy was approving the
11 proportion of the budget that would be
12 allocated to the advocacy function. And
13 that advocacy function had the expertise
14 to determine which organizations to work
15 with, and where, if any, sponsorships
16 were made.

17 Q. What role, if any, did you
18 have in overseeing key opinion leader
19 development?

20 A. Again, it's consistent with
21 the other areas, my principal
22 responsibility was to ensure that the
23 allocation of the overall investment was
24 weighted appropriately relative to the

1 other. So the end result in terms of
2 total investment in speaker bureau, or
3 speaker programs was -- became my -- I
4 had to endorse it. And be approved as a
5 proportion of the spend of the overall
6 company's budget.

7 Q. Who reported to you that
8 directly oversaw key opinion leader
9 development? Was it Frank DeMiro?

10 A. Frank DeMiro did report to
11 me, and he was involved in the
12 development of key opinion leaders for
13 the pain business. He worked in
14 conjunction with medical affairs and --
15 and occasionally R&D to identify the
16 right people.

17 Q. Who at medical affairs would
18 he have worked with to identify the right
19 key opinion leaders to speak on behalf of
20 Janssen's pain products?

21 A. In terms of identifying top
22 level faculty, these are faculty who
23 trained the speakers in partnership with
24 our medical team. Head of medical

1 affairs would have included -- I'm going
2 to just make sure I get the timing right.
3 Dr. Bruce Moskovitz. And Dr. Gary
4 Vorsanger. And any other members of
5 their staff, including medical science
6 liaisons who may know key opinion
7 leaders.

8 (Document marked for
9 identification as Exhibit
10 Janssen-Lin-9.)

11 BY MR. JANUSH:

12 Q. I'm going to have my
13 colleague give me his laptop. I'm going
14 to plug in, for the next exhibit, because
15 it's too cumbersome to print out. It's
16 an Excel file.

17 I'm going to plug in and
18 populate it on the screen. And we'll
19 produce it at the end of this deposition
20 as an electronic file that will be
21 attached to the deposition transcript.

22 THE VIDEOGRAPHER: All you
23 have to do is drag that window to
24 your right. It will pop up.

1 MR. JANUSH: This is JAN --
2 we're going to test my technology
3 capabilities.

4 MR. GALIN: You've already
5 demonstrated they're superior to
6 mine. I couldn't have set all
7 this up.

8 MR. JANUSH: This is what
9 took a bit of time.

10 A-ha. Okay. This is hard
11 because where's the mouse?

12 THE VIDEOGRAPHER: Go to the
13 right.

14 BY MR. JANUSH:

15 Q. All right. So can you see
16 this screen? This is Bates Number
17 JAN-00119068, and this is a 2012 brand
18 investment summary. Have you seen
19 documents like this before, Mr. Lin?

20 A. I have seen documents like
21 this, yes.

22 Q. Okay. And it looks like,
23 going to the left side, there is
24 strategic imperatives. And I'm going to

1 read some of this. "Drive broad and
2 competitive access and availability."

3 And then to the right side, "Provide
4 patient saving programs."

5 Do you see that?

6 A. Yes.

7 Q. Okay. And then it looks
8 like there's a -- I'm going to box it in,
9 I'm highlighting -- or, maybe not
10 highlighting, but "23.5 JU budget."

11 Does that stand for June
12 budget?

13 A. The term JU is used for June
14 update which is probably in the --
15 somewhere in the April to -- it refers to
16 generally the period of, if you're
17 looking at a snapshot, somewhere in the
18 April, May, June period.

19 Q. Okay. And then there's a
20 next column that says, "\$1.7 million to
21 cut," from whatever this June budget was;
22 is that right? Looking to cut from the
23 June budget on the column to the right?

24 A. So for clarity, I'm just

1 guessing, because these are scenarios.
2 But they appear consistent with an
3 exercise that brands would do if they're
4 trying to reduce the budget or at least
5 prioritize.

6 Q. And then on the right side,
7 do you see \$21.8 million budget. Do you
8 see that?

9 A. Yes.

10 Q. Okay. So we were just
11 earlier looking at a 2009 actual budget.
12 And then a 2010 October review of a
13 budget, a 2011 forecast going up to a
14 hypothetical \$44 million marketing
15 budget.

16 And now we're in 2012 and
17 we're looking at less than half of the
18 2011 forecasted budget; is that right?
19 At this \$21.8 million?

20 MR. GALIN: Objection to
21 form.

22 THE WITNESS: I would agree
23 that the number is roughly half of
24 what was on that hypothetical

1 proposed.

2 BY MR. JANUSH:

3 Q. Okay. Does that -- does
4 this \$21.8 million budget for 2012 fall
5 within the ballpark of your recollection
6 in terms of a significant drop between
7 2011 and 2012 in Nucynta's brand
8 investment plan?

9 A. I'm so many years out from
10 working on the brand that I can't speak
11 to the actual year-by-year change.

12 Q. Okay.

13 A. And what my -- because I
14 don't know that this was an actual -- I
15 don't know if this is where the actuals
16 were. But I see it as a scenario.

17 Q. Yeah. I'm going to possibly
18 hand you over the laptop to use your
19 Excel skills to view the actuals. But it
20 looks like there is a -- I'll blow this
21 up, budget as of 12/20. That seems to be
22 close to the end of the year, 12/20. And
23 it shows invoiced \$22,617,386 with an
24 expected invoice number of 288 -- or 98,

1 I can't read it well -- 396, an open
2 amount of \$419,755, and a sliver for no
3 purchase order of \$236,848.

4 Am I understanding that no
5 PO correctly?

6 A. That's what shows here.

7 Q. Okay. Invoiced 22,617 --
8 \$22,617,386.

9 What does invoiced mean?

10 A. The company received the
11 invoice, and most likely what happens --
12 well, what happens when you're invoiced
13 is you authorize payment for that
14 invoice.

15 Q. So more likely than not, the
16 notion of \$22,617,386 is an actual
17 number, right? It's an invoiced number,
18 it's actual, not just forecasted, once
19 it's invoiced?

20 A. In all likelihood, it would
21 be -- those invoices would be paid.

22 Q. And there's a tab for
23 actuals that is really hard to read. So
24 we're just going to do it a little

1 differently. And we're going to scroll
2 up to the top and see what I can find on
3 filtering, if I could filter. Give me
4 one second. This is Decile.ten. This is
5 a vendor of the marketing department?

6 MR. GALIN: Objection to
7 form.

8 THE WITNESS: It is a
9 third-party professional promotion
10 agency.

11 BY MR. JANUSH:

12 Q. Okay. So Decile.ten for
13 2012, and there's a spend category,
14 \$462,663.57. What would this -- what
15 would this company be doing? I see on
16 the doc header, "Webcast, speaker
17 trainings," I see "clinical educators."
18 Can you shed light on Decile.ten?

19 A. Yeah. I can shed more light
20 on Decile.ten than I can on the line
21 items that are on here.

22 Q. Well, here's some line
23 items. I can blow up for you.

24 A. Okay.

1 Q. Speaker deck update, webcast
2 speaker training, Prescribe Responsibly
3 phase, sales training contracting,
4 Nucynta IR pain policy slide deck
5 development, Steve Stanos honorarium,
6 appears to be paid through Decile.ten.

7 Let me pause there. So this
8 is an instance that instead of
9 utilizing -- instead of Janssen directly
10 paying Dr. Stanos, Dr. Stanos was paid
11 through Decile.ten. Is that fair to say
12 that that's what this line item shows?

13 A. You know, I have no
14 recollection of this transaction.

15 Q. I'm not asking if you have a
16 recollection. I'm asking if that's what
17 it shows, because there's a PO text.
18 That's purchase order text, right? And
19 there's a document number. That's
20 usually a purchase number, right, on the
21 left?

22 A. Okay.

23 Q. I'm asking you. I'm asking
24 you. I'm just going through it. And it

1 says spend, \$2,750.

2 Do you see that?

3 A. Yes.

4 Q. And it's under the

5 Decile.ten account.

6 Do you see that at Column F?

7 A. Yes.

8 Q. Okay. So I'm not trying to
9 speculate either. I'm just trying to
10 conclude if it's correct that Decile.ten
11 billed an invoice for Steve Stanos
12 honorarium for Nucynta ER.

13 MR. GALIN: Objection to
14 form.

15 BY MR. JANUSH:

16 Q. Based on this.

17 A. Based on what's listed here,
18 it does appear there's a line item where
19 a -- I'm going to guess it's a physician
20 customer, was paid to do a service for
21 the brand.

22 Q. Okay. So going back to my
23 earlier question, who is Decile.ten?
24 What did they do for you? Can you shed a

1 little more light on it?

2 A. Yeah. Broadly speaking,
3 Decile.ten focuses on helping brands
4 develop their promotional message,
5 particularly with a focus on speaker
6 programs. I think they are also in
7 managed care communications, where
8 they're -- they're helping brands talk to
9 payers. So they're -- the main
10 distinction is that they are different
11 than the agency that would help develop a
12 promotional message for use on an iPad
13 with a doctor in their office.

14 Q. Okay.

15 MR. JANUSH: Can you help me
16 get back to undo this?

17 THE VIDEOGRAPHER: Over
18 here?

19 MR. JANUSH: Yeah. I want
20 to get -- undo that. This should
21 be on -- I wish I had it all on
22 one screen because...

23 We're going to need to take
24 a brief break for this technical

1 issue.

2 THE VIDEOGRAPHER: The time
3 is 2:30 p.m. Going off the
4 record.

5 (Short break.)

6 THE VIDEOGRAPHER: We are
7 back on the record. The time is
8 2:37 p.m.

9 MR. JANUSH: Thank you for
10 accommodating me and the technical
11 issue I encountered a moment ago.

12 MR. GALIN: No worries.

13 BY MR. JANUSH:

14 Q. Earlier I had asked about
15 the coupon voucher program. And I'd
16 asked if you knew who -- who managed it.
17 And I threw out the name McKesson. I've
18 actually found through this budget that
19 it was McKesson Specialty Arizona Inc.

20 Does that name ring a bell
21 to you in any way? No?

22 A. McKesson rings a bell now,
23 But Specialty Arizona Inc., no.

24 Q. All right. Now, scroll with

1 me, I'm going to move a couple columns to
2 the right. First of all, there's a bunch
3 of purchase orders, and then to the right
4 are purchase order texts. And it seems
5 to be -- it seems to indicate that this
6 is primarily Nucynta voucher provides up
7 to 10 FR -- I think that's the ten free
8 pills. Does that sound right to you?

9 A. That -- that sounds
10 familiar, yes.

11 Q. And then the Nucynta savings
12 card offers out-of-pocket savings, I'm
13 assuming is what would have been stated
14 after that; is that right?

15 A. Yes.

16 Q. Okay. And it's all 2012,
17 I'm going to represent to you -- first of
18 all, we're only in a 2012 budget. And
19 the dates range from 12/27/2012 -- or I
20 should say from October 15, 2012, to
21 12/17/2012, and in a two-month period,
22 the spend column reflects a sum of
23 \$2,124,480.99.

24 Do you see that at the

1 bottom in the sum?

2 A. Yes.

3 Q. Okay. What would this
4 expenditure -- would this expenditure
5 have been paid to McKesson to manage the
6 coupon or -- or rebate program for
7 patients?

8 MR. GALIN: Objection to
9 form.

10 THE WITNESS: Based on the
11 POs that I see and what limited
12 text there is, I am going to
13 conjecture that this is for the
14 management of those programs.

15 BY MR. JANUSH:

16 Q. Okay. I'm going to move
17 into a different screen. Graphical.
18 This is under the graphical REP slide or
19 page within this Excel -- Excel file.
20 And it starts at the top with budget as
21 of 12/20. Invoiced \$22,617,386.
22 Expected invoice, \$288,396. Open, 419 --
23 \$419,755. No purchase order \$236,848.
24 And a budget total of \$23,562,385. And

1 it looks like your group was over budget
2 by \$1.762 million.

3 Does that look right to you
4 or what I'm reflecting accurate -- an
5 accurate representation of what's on this
6 screen based on this document?

7 A. At a very high level, it
8 looks like -- I would have to check the
9 formulas, but it would appear, if the
10 math is right, that there's a scenario
11 where the brand could be over budget.

12 Q. Now, I'm just trying to
13 focus on some big picture payments here.
14 And I see Weber Shandwick purchase order
15 for \$172,295, but it's just an initial --
16 I believe an initial purchase order. And
17 when you scroll down, the sum looks like
18 it's \$603,000. I'm going to make sure
19 I'm reading that column right by
20 scrolling up to total. Yeah, total
21 purchase order. Total PO, \$603,000 in
22 green allocated to Weber Shandwick with
23 Frank DeMiro as the assigned Janssen
24 employee for this account.

1 What services did Weber
2 Shandwick provide to you generally?

3 A. Weber Shandwick is a PR
4 communications firm in healthcare.

5 Q. So what kind of services
6 would they have provided as it concerned
7 Nucynta?

8 A. Without their exact scope of
9 work in front of me, the kinds of things
10 they generally do are to -- PR firms will
11 be engaged in liaise with healthcare
12 publications, the healthcare press, life
13 sciences press. And their objective is
14 to understand what are the potential
15 venues or advertising opportunities that
16 a brand could potentially participate in.

17 Q. Okay. Earlier we talked
18 about national advocacy. We talked about
19 programs, maybe not national, but
20 advocacy in general. And here is,
21 "Develop national" -- and it's at Line
22 Item 232. "Develop national pain policy
23 platform to align HPADs and SGA." What
24 does that stand for? To align HPADs and

1 SGA?

2 A. I'll start with the second
3 one. SGA, State Government Affairs. And
4 HPADs, I just -- I don't recall what that
5 stands for. It's an acronym for a team
6 of people that -- there was only a few --
7 a handful of them. They -- I want to say
8 they dealt with health policy. That's
9 the only recollection that I can think of
10 right now.

11 Q. Okay. And I want to jump
12 down to Line 255. And these subtitles
13 that are in black background with white
14 font, these are section headings, under
15 which different line items follow; is
16 that right?

17 A. They are indeed. They look
18 like groupings.

19 Q. Groupings. Okay. So let's
20 talk -- start with the grouping, "Advance
21 awareness of undertreatment of pain."

22 Do you see that?

23 A. Yes.

24 Q. Okay. And the owner of that

1 grouping is Lisa Ferguson and Frank
2 DeMiro, it looks like. Do I have that
3 right?

4 A. Yes.

5 Q. Okay. And looking at,
6 "Advance awareness of under treatment of
7 pain," the entities that put in purchase
8 orders and are in this grouping are
9 Nucynta -- are Ketchum, Inc. That's a
10 public relations firm, right?

11 A. Yes.

12 Q. Nucynta Smart Moves, Smart
13 Choices toolkit. That was actually a
14 website, Smart Moves, Smart Choices;
15 isn't that right?

16 A. My recollection is there was
17 a website, but there was also a press
18 kit.

19 Q. Okay. This is -- this is --
20 I think you're right. This is a toolkit
21 and a DVD, it looks like, postage for
22 Smart Moves, Smart Choices. And then
23 Smart Moves, Smart Choices fulfillment.
24 What would that stand for, fulfillment?

1 A. In the -- in the lingo of
2 these brands, fulfillment would be if a
3 customer requested something through a
4 business reply card or maybe went online
5 and to something and said, "I'd like to
6 get something." It's usually an
7 educational piece -- piece of educational
8 material.

9 Q. Okay. And along with,
10 "Advancing awareness of undertreatment of
11 pain," comes Weber Shandwick's fee.

12 Do you see that?

13 A. Yeah.

14 Q. Okay. And I also see
15 something called "PAINweek Curtain
16 Raiser." What's that?

17 A. I don't know how these are
18 used together. Curtain raiser is a PR
19 type of term. When there's a --
20 something akin to national breast cancer
21 awareness week. There's a -- it's when
22 there's a callout to focus on a
23 particular subject in healthcare.

24 Q. Okay. I'm trying to scroll

1 to see if there's anything else that I
2 want to address.

3 So there's a subheading at
4 Line 200, "Obtain hospital stocking and
5 formulary access." And within that
6 section comes "Joint Commission book
7 program, \$200,000."

8 What does that pertain to?

9 A. I don't recall exactly what
10 that program was. I'm familiar with the
11 term "Joint Commission." That's --

12 Q. It's not just a term. It's
13 the hospital accreditation group,
14 correct?

15 A. Yeah, that sounds right.

16 Q. Joint Commission is the
17 group that led the effort to create pain
18 as a fifth vital sign in or about year
19 2000; is that right?

20 MR. GALIN: Objection to
21 form.

22 THE WITNESS: I can't speak
23 to the accuracy of that.

24 BY MR. JANUSH:

1 Q. Okay. Do you know why you
2 were paying in year 2012 \$200,000 to the
3 Joint Commission?

4 A. Based on what we've seen
5 here, I can't -- I can't be certain what
6 that is.

7 Q. I see something at Line 165,
8 a new subheading group, "Accelerate
9 regional pull-through of national
10 formularies."

11 What does it mean to
12 accelerate regional pull-through of
13 national formularies?

14 A. When a health plan puts a
15 product, for example, on Nucynta and
16 they've deemed it to be in a particular
17 tier, and they've put guidelines around
18 it as to conditions of use, for example
19 if you failed a generic -- you have to
20 try a generic first, but if the generic
21 didn't work, then you can try a branded
22 product.

23 That's -- that might be a
24 condition of formulary approval on a

1 national level. But all these plans
2 have -- they call them children plans at
3 various regions in the country. And from
4 a managed -- from a practicality
5 standpoint, even if we're approved -- a
6 brand is approved at the national
7 formulary level, unless the brand makes
8 inroads at the regional level, the
9 doctors in that region -- or the patients
10 in that region don't get to actually
11 experience the particular rebate/co-pay
12 that was negotiated at the national
13 level.

14 So it's an extra step to do
15 that. And so that's more than likely
16 what that means, is to make sure that the
17 national coverage is reflected at the
18 regional level.

19 Q. And I see that that one --
20 I've added the sums, and I've grayed it
21 out, so you can see -- I'll follow with
22 my mouse, from the bottom to the top of
23 that category. I've added this up, or
24 Excel has. And it looks like \$1,073,831

1 has been allocated to this access and
2 pull-through issue.

3 Any idea why, within that
4 there would be a line item for the
5 American Journal of Managed Care
6 publication for \$150,000 budget?

7 MR. GALIN: Objection.

8 BY MR. JANUSH:

9 Q. Not actual, but budget. The
10 actual is only \$52,700.

11 A. I don't recall what that
12 line item would be specifically referring
13 to, no.

14 Q. And Profero agency fee,
15 \$215,000. What would Profero agency fee
16 be doing to accelerate regional
17 pull-through of national formularies?

18 A. Profero specializes in
19 developing educational materials for
20 offices, specifically for use in doctors'
21 offices so that -- well, let me -- let me
22 be accurate. Either materials for a
23 sales rep to use with an office or
24 material to leave behind at the office.

1 Such material would
2 basically be designed to educate the
3 office on what is the coverage of a
4 product like Nucynta in the plans that
5 are most dominant in their geography.

6 Q. Okay. Here at Line 223, the
7 subheading is, "Advocate for responsible
8 prescribing through nonbranded tools."
9 And we have Prescribe Responsibly app.
10 Is that the Prescribe Responsibly iPad
11 app for sales reps, or is this the
12 Prescribe Responsibly web program
13 available to the public?

14 A. I don't know exactly which
15 tactical execution item that was. I
16 can't speak to that.

17 Q. And Prescribe Responsibly,
18 just so we're clear -- we'll talk about
19 it a little later in greater detail, but
20 that's the website created by Janssen
21 that was an unbranded tool that linked
22 from Nucynta's website -- linked from
23 Nucynta's -- Nucynta's website, and
24 addressed pain and chronic pain issues

1 and put publications on line for patients
2 to read; is that right?

3 MR. GALIN: Objection to
4 form.

5 THE WITNESS: I -- I can
6 definitely say I was -- I am
7 familiar with the Prescribe --
8 Prescribe Responsibly initiative.
9 Whether or not -- and I believe
10 there was a website. Whether --
11 whether Nucynta -- you could link
12 it from Nucynta.com or the exact
13 resources that were offered on it,
14 I can't speak to that with any
15 accuracy.

16 BY MR. JANUSH:

17 Q. Okay. Who would be the best
18 person to talk to, during your tenure,
19 about Prescribe Responsibly?

20 Would it be Ron Kuntz? He
21 is listed as the owner in that
22 subcategory. That's why I'm asking.

23 A. So I think he is potentially
24 one to speak to. But again, I -- since

1 this is a living breathing document at
2 the time, it could have been -- there is
3 on occasion where you have a swap-out in
4 responsibilities. So I think he would be
5 one.

6 Q. Granted it is December 20,
7 2012, is the last date entered on this
8 document. So your year-end -- your --
9 when does your year end at Janssen?

10 A. When I was there it was
11 December.

12 Q. Right. That's what I'm
13 getting at.

14 A. All -- all I'm saying is
15 that what we're -- what we're looking at
16 here is a -- I think it's important to
17 put into context that the spreadsheet
18 you're looking at here has a combination
19 of things that are run from a financial
20 system of invoices paid. And also
21 reflects what a brand team was looking at
22 in order to drive closure of those POs.

23 So who was the subject
24 matter expert may or may not have been

1 the name listed. When you -- when you
2 have outstanding POs and you want to
3 chase invoices at the end of the year,
4 which is a common practice in a brand,
5 oftentimes the responsibility is divvied
6 up between various people to essentially
7 chase down vendors for -- for invoices.
8 So I do think it's important to put that
9 in context, because a lot of what's shown
10 here has more to do with just keeping
11 records straight, landing the budget
12 number accurately.

13 Q. So I'm going to go to the
14 first top category in the 2012 brand
15 investment summary. It's in black. The
16 group heading is execute leading edge
17 peer-to-peer education. Do you see that?

18 A. Yes.

19 Q. And in blue next to it, the
20 strategic imperative says, "Establish
21 Nucynta as new standard in moderate to
22 severe pain management."

23 Do you see that?

24 A. Yes.

1 Q. And the first line item is,
2 "Live speaker programs (including
3 regional hot spots) with a \$4.5 million
4 budget," it looks like, but then I
5 won't -- I'll go directly to the actual
6 to see what that is.

7 "Invoiced 4 million." Do
8 you see that?

9 A. Yes.

10 Q. Okay. So this would tend to
11 reflect that \$4 million had been
12 invoiced, and according to your earlier
13 testimony, should be paid for live
14 speaker programs that had thus far been
15 billed as of this point in time in 2012,
16 right?

17 A. That would be my conclusion.

18 Q. Okay. And the vendor for
19 these live speaker programs is a company
20 by the name of MedForce. Do you see
21 that, it's right in the line D?

22 A. Yes, I see that.

23 Q. Who is MedForce, what did
24 they do? Did you work with them

1 personally?

2 A. I did not work with MedForce
3 personally. MedForce is a third-party
4 agency that manages speaker programs for,
5 fair to say a good number, if not a large
6 number, of pharmaceutical manufacturers.

7 They essentially handle
8 logistics for setting up a speaker
9 program.

10 Q. What does that mean, to
11 handle logistics? Would -- would the
12 speakers be paid through MedForce?

13 A. The part about logistics
14 that I can -- that I'm familiar with is
15 if, for example, I was a sales rep, and I
16 was going to hold a speaker program, I
17 would choose the speaker from the
18 available list of speakers. I would call
19 up MedForce and say, Dr. Speaker and I
20 have agreed to do a program on
21 February 25th here in Princeton,
22 New Jersey. MedForce would help secure a
23 location or a venue that was appropriate
24 for a speaker program that was within

1 healthcare compliance guidelines and they
2 would set it up.

3 And then once it was set up,
4 the representative could distribute or
5 communicate through e-mail invitations or
6 verbal invitations to the customers that
7 he or she wished to invite. MedForce
8 would take care of the travel
9 arrangements of the speaker. Typically
10 they are more local, but it would ensure
11 that the program was -- all the
12 logistics, from the speaker getting there
13 to the AV equipment being there, to the
14 restaurant menu.

15 Q. And just under that live
16 speaker program, budget number for
17 MedForce, there is full service for
18 meeting direct?

19 A. Yes.

20 Q. Then there's Nucynta 2011
21 speakers bureau execution credit. Do you
22 know what an execution credit is?

23 A. Well, typically if -- if the
24 speaker bureau, you know, the -- the

1 vendor might invoice -- they may invoice
2 too much, because it was an anticipated
3 number of programs to execute. And if
4 you don't use it -- if they don't
5 actually hit it, then there's a credit.

6 Q. Okay. And then it gets to
7 KOL stakeholder database and decile.ten
8 is the vendor. What is the KOL
9 stakeholder database?

10 A. I'm not -- it -- it doesn't
11 ring a bell right now. But part of
12 the -- the desire of a brand is to make
13 sure that you -- that the brand is able
14 to categorize all the different folks
15 that are influential in a particular
16 area. So a typical KOL database may have
17 a person listed as very good for the
18 neurology community, or very good for
19 let's say surgeons. Just to give a
20 little bit of structure.

21 Q. And in this instance, at
22 least for Line 9 in the 2012 brand
23 investment summary, decile.ten is listed
24 as the vendor who managed this KOL

1 stakeholder database for Nucynta?

2 A. It appears like that, yes.

3 Q. And moving down one line to
4 Line 10, core message development speaker
5 deck update. And it looks like I can
6 skip that because there's not an invoice
7 associated with it. So I want to be
8 correct in how I deal with that.

9 But it may be that the
10 invoices are here. Project -- they are.
11 Project management and consultancy
12 services for Q1, 2, 3 and 4, all
13 associated with decile.ten and all
14 invoiced for 1, 2, 3 and 4. And it looks
15 like \$99,952 was associated with project
16 management and consultancy services.

17 What kind of project
18 management and consultancy services did
19 decile.ten provide with respect to core
20 message development and speaker deck
21 update?

22 A. So the speaker bureau, the
23 folks on the speaker bureau delivered
24 their programs, these promotional

1 programs from an approved -- what we
2 called a core deck. The core deck was
3 developed and maintained by a firm, in
4 this case, decile.ten.

5 One of the important things
6 about the speaker deck is that any change
7 to that deck required a thorough edit
8 process, resubmission into a -- into a
9 copy review process, and then was
10 disseminated again to the speakers.

11 Q. And, in fact, in addition to
12 project management and consultancy
13 services, deck updates which you were
14 just addressing was separately invoiced.

15 A. Okay.

16 Q. And it looks like \$115,421
17 was listed as the total purchase order.
18 So that would be for updating the
19 PowerPoint slides --

20 A. Yeah.

21 Q. -- for key opinion leaders
22 to talk about?

23 A. Yes.

24 Q. Okay. And then there's

1 something called Interactive Presentation
2 Builder 3.0 with an invoice for \$122,300.
3 What's that, if you can recall?

4 A. My recollection of
5 Presentation Builder was it allowed a
6 trained speaker to decide the order of
7 how they wanted to handle the program.
8 So for example, if a speaker decided,
9 let's say for discussion's sake, the --
10 the audience was more orthopedic
11 surgeons, then it would be incumbent upon
12 that speaker -- the interest level of the
13 audience would be more focused on
14 immediate release Nucynta because they're
15 focused on postoperative pain management.
16 If the audience was a pain specialist,
17 you might have more of it be Nucynta
18 extended-release.

19 So it just simply allowed
20 them to say, I'm going to take the big
21 chunk and put it upfront, and -- they
22 couldn't change the content. They can
23 only just change the order of different
24 sections.

1 Q. Got it. Okay. And as to
2 that. I'm going to scroll back up. That
3 would have been \$122,300 invoiced. Do
4 you see that?

5 A. I do.

6 Q. Now, we're going to get to
7 some other topics. At Line 39, "Deploy
8 differential resourcing to drive local
9 market opportunities."

10 Do you see that?

11 A. Yes.

12 Q. And then the next subheading
13 is, "Product theaters, AAPM, APS, AANP,
14 PAINWeek," and a projected \$400,000
15 budget. And again, that's a subheading
16 under which some line items now appear.
17 Do you see at Line 41, the first line
18 item is, "2012 APS product theater"?

19 A. Yes.

20 Q. And APS stands for the
21 American Pain Society, doesn't it?

22 A. Yes.

23 Q. And so what is a product
24 theater of the APS?

1 A. My recollection is that a
2 product theater is when a manufacturer or
3 a brand can pay for a slot in the
4 meeting. You are basically buying a --
5 buying a spot on the schedule to deliver
6 a promotional message.

7 Q. Okay. And for that there's
8 a purchase order of \$143,457.

9 Do you see that?

10 A. I do.

11 Q. Okay. And so there's also a
12 2012 AAPM product theater. Would that be
13 similar to APS theater where Janssen is
14 buying a spot to deliver a promotional
15 message about Nucynta?

16 A. That would be similar.

17 Q. Okay. And they are --
18 sorry, I scrolled out. But there we have
19 a charge of -- an invoice of \$139,129; is
20 that right?

21 A. It looks correct.

22 Q. Okay. And then there's a
23 smaller charge under that for MPR live
24 report at AAPM meeting, \$37,450. What's

1 an MPR live report at an AAPM meeting?

2 A. I don't know what an MPR
3 line report is.

4 Q. Okay. Then we'll skip it.
5 We'll go down to 2012 PAINWeek product
6 theater. Similar to what you testified
7 about regarding APS and AAPM? Would it
8 be the case that Janssen was paying
9 \$44,400 to the PAINWeek group to get in a
10 promotional spot to discuss Nucynta?

11 A. I believe that's what that
12 would be intended for, yes.

13 Q. Okay. And now here comes
14 one that's a little bigger. Line 48, and
15 the subheading is, "Competitively
16 differentiate versus oxy."

17 Do you see that?

18 A. Yes.

19 Q. And under that is, "Vendor
20 ICC." Who is ICC?

21 A. ICC stands for Integrated
22 Communications Corporation. It's an
23 ad -- professional advertising company
24 under one of the large healthcare

1 conglomerates. I don't remember which
2 one.

3 Q. And it looks like the owner
4 of this is a new name for us, Paul
5 Lowman. Do you see that?

6 A. I do.

7 Q. Who is Paul Lowman within
8 Janssen?

9 A. Paul Lowman at the time was
10 a product manager. So my -- in looking
11 at what's here, he was probably assigned
12 to just handle the invoicing.

13 Q. Okay. And under Paul
14 Lowman, the owner is Tricia Yap
15 associated with the line item for agency
16 fees. And this is Line 50 on this
17 spreadsheet. And I'm going to scroll
18 over.

19 It looks like agency fees
20 from ICC to competitively differentiate
21 Nucynta versus oxy totaled \$2,882,043.
22 Does that look right? Am I representing
23 this correctly?

24 A. That -- that looks accurate.

1 Q. Okay. So that's -- if
2 hypothetically this budget was
3 \$23 million or in that range, we're
4 talking about an amount greater than 10
5 percent of the total annual marketing
6 brand investment budget for Nucynta to
7 differentiate Nucynta as compared with
8 oxy; is that right?

9 A. I think it's accurate to say
10 that roughly two point -- I forget the
11 exact number.

12 Q. 2.8 million --

13 A. \$2.8 million or
14 \$2.9 million --

15 Q. Of the total --

16 A. -- of the total was spent on
17 a scope of work that was attributed to
18 ICC, professional communications agency
19 to help develop the promotional assets
20 that were utilized by the brand, some of
21 which we looked at examples of.

22 Q. Okay. I'm just trying to be
23 careful here.

24 All right. So the biggest

1 line item in the entire brand investment
2 strategy appears to be the live speaker
3 programs at \$4 million. And the next two
4 items that are above \$2 million are the
5 McKesson rebate program or coupon program
6 and this comparison with oxy.

7 Fair to say that, number
8 one, funding your speaker program was
9 pretty important to Janssen's overall
10 brand investment strategy to promote
11 Nucynta?

12 A. Peer-to-peer education was a
13 critical part of the marketing mix for
14 driving awareness and adoption for
15 Nucynta and Nucynta ER.

16 Q. Fair to say that funding the
17 rebate program in order to get better
18 access for patients to be prescribed or
19 to want to pick up and pay for at the
20 co-pay level Nucynta was important to
21 Janssen's brand strategy to promote
22 Nucynta?

23 MR. GALIN: Objection to
24 form.

1 THE WITNESS: I think
2 supporting -- it was important to
3 the brand as a newcomer to the
4 category to support good access
5 for patients and provide customers
6 with the ability to help their --
7 their patients get started on a
8 brand that didn't have the best
9 coverage at the time of launch.

10 BY MR. JANUSH:

11 Q. Is it also fair to say that
12 it was really important for Janssen to
13 compete against oxy and that's why, in
14 2012, it permitted the brand to be
15 invoiced \$2,882,433 to advance those
16 endeavors?

17 MR. GALIN: Objection to
18 form.

19 THE WITNESS: I think -- I
20 think it's really fair to say that
21 when launching a new entrant in a
22 very crowded and complacent
23 market, that working -- seeking
24 the help of an advertising agency

1 to help differentiate the brand in
2 the eyes of the customer is a
3 really important step towards
4 successful adoption.

5 BY MR. JANUSH:

6 Q. Okay. Now, I'd like you to
7 answer my question though. My question
8 wasn't about the really competitive,
9 crowded market. My question was about
10 oxy and the fact that you just testified
11 about a really competitive crowded
12 market, and yet there is an effort to
13 only differentiate against oxy, led me to
14 ask my specific question.

15 A. Sure.

16 Q. Is that fair?

17 A. Sure.

18 MR. GALIN: Objection to
19 form.

20 BY MR. JANUSH:

21 Q. So was it important for
22 Janssen to competitively differentiate
23 Nucynta vis-à-vis oxy?

24 A. I'll qualify to say that the

1 oxy -- oxycodone or OxyContin was
2 generally regarded as a standard of care.
3 And as a new entrant, differentiating of
4 standard of care is absolutely important.

5 Q. And that's why we continue
6 to see efforts to differentiate between
7 Nucynta and oxy in marketing materials,
8 because it was really important for
9 Janssen to do so, right?

10 MR. GALIN: Objection to
11 form.

12 THE WITNESS: I'm just
13 conjecturing because we're not
14 looking at a specific piece. But
15 it's important to differentiate a
16 new entrant based on the clinical
17 data using all the players in that
18 clinical trial and showcase
19 efficacy and tolerability.

20 BY MR. JANUSH:

21 Q. I'm going to move onto
22 another topic since this jammed up again.
23 I covered a lot on this budget, so we'll
24 move forward.

1 (Document marked for
2 identification as Exhibit
3 Janssen-Lin-10.)

4 BY MR. JANUSH:

5 Q. I'm marking Lin Exhibit 10.
6 It's Bates number is JAN-MS-01049919.
7 This is an e-mail -- there
8 you go, sir. Sorry.

9 MR. JANUSH: Counsel. One
10 for you. One for you.

11 BY MR. JANUSH:

12 Q. This is an e-mail from you
13 to a large list of recipients. And I'll
14 try and shrink this a bit. All right.
15 It's dated 1/29/2012, and the subject is
16 pain CSO team recruiting briefing.

17 This is concerning the
18 contract sales organization. That's what
19 CSO stands for, right?

20 A. That's right.

21 Q. And this is -- more
22 specifically, this concerns the Quintiles
23 provided or staffed contract sales
24 organization that we spoke about earlier

1 this morning that comprised the pain
2 force; is that right?

3 A. That's right.

4 Q. Okay. And in this e-mail,
5 you are advising colleagues that "this
6 e-mail contains pertinent information
7 regarding our upcoming Quintiles pain
8 representative cluster meetings. Please
9 take the time to familiarize yourself
10 with the contents and attachments.
11 During Monday's preparation call, our
12 Quintiles partners will review the
13 remaining details regarding onsite
14 logistics."

15 And moving further below,
16 you address as background, "As you have
17 heard from recent communications,
18 promotion of Nucynta ER and Nucynta in
19 2013 will be assumed by a standalone pain
20 sales team. This team will be staffed
21 and run by Quintiles and will collaborate
22 closely with the Janssen pain
23 organization."

24 I'll pause there for a

1 moment. I was going to ask you a
2 question about the composition of this
3 team, but I see it's answered in the very
4 next paragraph. 77 territory
5 representatives and seven district
6 managers and one national leader
7 comprised this pain force; is that right?

8 A. Yep, that's right.

9 Q. And so at this time, when
10 this pain force transitioned to Nucynta
11 from Quintiles, did Janssen 100 percent
12 do away with having their former sales
13 reps that covered Nucynta continue to
14 detail Nucynta? In other words, did the
15 pain force take over 100 percent for the
16 nation all detailing efforts concerning
17 Nucynta IR and Nucynta ER?

18 A. If recollection of the
19 timeline is correct, the hiring took
20 place during December. Quintiles hired
21 the sales team based on qualifications
22 that were given to them by Janssen.

23 The Janssen team that
24 previously sold Nucynta ER and Nucynta

1 essentially were responsible for the
2 product transitioning to a new rep in the
3 first quarter of 2013. The
4 representatives hired by Quintiles, I
5 can't remember the exact date when 77
6 were all on board, but suffice it to say
7 there's about a quarter transition and
8 there's about a quarter of when there's
9 really very inconsistent coverage of a
10 customer base.

11 Q. Fair enough. So, you went
12 from a pain or a Nucynta sales force that
13 comprised some numbers of hundreds of
14 detailers of sales reps that were
15 promoting Nucynta, to 77 salespeople with
16 seven district managers and one national
17 leader?

18 MR. GALIN: Objection to
19 form.

20 BY MR. JANUSH:

21 Q. Is that right?

22 A. We transitioned from a sales
23 force that had three products, the other
24 two being cardiovascular and metabolism,

1 and the pain product, to a standalone of
2 a sales force that just focused on pain.

3 Q. Going back -- thank you for
4 that clarification, but going back to my
5 question.

6 That other sales force,
7 notwithstanding how many other products
8 they covered, numbered into the hundreds
9 of sales folks that were detailing
10 Nucynta; is that right?

11 A. That's generally accurate,
12 yes.

13 Q. Do you remember how many
14 hundreds?

15 A. I don't remember the exact
16 number. My -- my recollection is it's
17 somewhere north of 500. Probably shy of
18 somewhere under a thousand.

19 Q. Okay. Fair to say that
20 77 salespeople, no matter how skilled
21 they may be, can't cover the entire
22 country?

23 A. These 77 were deployed
24 nationally in all major metropolitan

1 areas where there was a concentration of
2 relevant prescribers.

3 Q. I appreciate that. That's
4 another way of saying that these 77
5 weren't allocated to cover the entire
6 country, right?

7 A. For purposes of that
8 product, they were covering, in my
9 estimation, most of the country.

10 Q. Because they were covering
11 areas where prescribers were prescribing
12 Nucynta?

13 A. They were covering areas
14 where prescribers were covering -- they
15 were writing Nucynta and Nucynta ER. And
16 because there was a population of
17 treaters of pain.

18 Q. We're going to get back to
19 this very topic in just a short bit of
20 time. Okay?

21 A. All right.

22 Q. Before I move on to the next
23 exhibit, I want to ask some questions
24 about this Quintiles, this transition to

1 Quintiles.

2 What was your personal role
3 in terms of hiring the members of the
4 Quintiles pain force?

5 A. My role as the franchise
6 leader was that I chose, in conjunction
7 with other leaders -- I made the
8 recommendation to choose Quintiles as the
9 contract sales organization.

10 My role also extended into
11 aligning with others in our organization,
12 the qualifications, the profile and the
13 deployment scenario, all of which served
14 as the -- think of it as a, this is the
15 specifications to hand over to the
16 contract sales organization Quintiles,
17 from which they actually began to staff
18 their team based on our requirements.

19 Q. Did these salespeople obtain
20 Janssen e-mail addresses to communicate
21 within Janssen?

22 A. Yes.

23 Q. Did they have any offices
24 within Janssen or were they remote

1 employees?

2 A. Well, all sales
3 representatives and district managers
4 are, by definition, field based so they
5 don't have offices.

6 Q. And why hire and train an
7 entirely new sales force, a standalone
8 pain force employed by Quintiles, instead
9 of utilizing the Janssen employees that
10 were previously trained, some of which
11 who had been trained for years in
12 detailing Nucynta?

13 A. Competing priorities.
14 Janssen internal medicine was in the
15 middle of a launch of two important
16 blockbuster products. They needed to
17 basically refocus all efforts on those
18 two particular opportunities which had a
19 lot of overlap in customer base and they
20 were deemed to be of more strategic
21 importance to the future of the
22 organization.

23 Q. But you had some great
24 salespeople who were ranked highly within

1 the company who were doing a good job and
2 made their inroads with doctors' offices
3 and were high performing and awarded
4 sales reps detailing Nucynta, didn't you?

5 A. There were, in fact, people
6 that were very experienced with pain.

7 Q. And so why not transition
8 the very best of the best to move over to
9 your new pain sales force and have other
10 people trained to cover the -- the other
11 general health products that you were
12 addressing, concerning cardiac care and I
13 forget what the other one was?

14 A. Metabolics.

15 Q. Metabolics.

16 A. Type 2 diabetes. I think in
17 an ideal world as you've described it is
18 how one might approach it. But one of
19 the other key philosophies when you deal
20 with a large sales organization, is that
21 we try to actually minimize change
22 because those representatives have --
23 they know a particular geography very
24 well, they know the health ecosystem in

1 that area, and as you're focusing on
2 launching two new products that have
3 significant opportunity in competitive
4 profiles -- with competitive profiles,
5 the overriding factor is knowledge of a
6 particular marketplace trumps specific
7 knowledge about one therapeutic area.

8 Q. However, you weren't going
9 out with a mindset to hire skilled sales
10 representatives from Quintiles that had
11 prior experience detailing pain, pain
12 medicine?

13 MR. GALIN: Objection to
14 form.

15 THE WITNESS: Are you -- are
16 asking me if that was a criteria?

17 BY MR. JANUSH:

18 Q. Yeah.

19 A. If -- if you're asking me if
20 we sought to hire -- if Quintiles sought
21 to hire representatives with pain
22 background --

23 Q. I can hear you at the same
24 time. I'm not being rude.

1 A. If you're asking me if
2 Quintiles sought to hire folks with a
3 pain background, that was one -- I
4 believe, if my recollection serves
5 correctly, that was one of the criteria
6 that we asked for in the hiring profile.

7 Q. Fair enough. So the nuance
8 I would suggest -- I would assert instead
9 is that while pain -- experience with
10 pain may have been a screening criteria,
11 experience with pain in the Schedule II
12 opioids space was not a screening
13 criteria; isn't that right?

14 MR. GALIN: Objection to
15 form.

16 THE WITNESS: I can't speak
17 specifically right now to the job
18 description. It may not have been
19 a show stopper. If recollection
20 serves me correctly, it was
21 absolutely something that was
22 highlighted as something desirable
23 to have.

24 BY MR. JANUSH:

1 Q. Okay. This is your e-mail,
2 turning -- turning back to it.

3 MR. GALIN: You grabbed my
4 version.

5 MR. JANUSH: Sorry, sorry,
6 sorry.

7 MR. GALIN: I just want to
8 follow along.

9 MR. JANUSH: Which exhibit?
10 My apologies.

11 MR. GALIN: No worries. I
12 just needed it to follow along.

13 BY MR. JANUSH:

14 Q. Exhibit 10. "The ideal
15 candidate" -- it's the last sentence,
16 second-to-last sentence. I'm
17 highlighting it. "As you'll note in the
18 job description, experience in pain was a
19 screening criteria, but was not limited
20 to experience in the C-II market.
21 Selling experience within a specialty
22 market is also important."

23 Do you see that?

24 A. Yes.

1 Q. So we're not that far apart
2 from each other. You're saying that pain
3 was a screening criteria. And I'm saying
4 prior experience in the C-II market was
5 not a limiting factor here, not in your
6 words. Now that you've read your e-mail,
7 do you agree where I'm coming from?

8 A. I can see where you're
9 coming from, but to be totally accurate
10 and fair, we should look at the job
11 description.

12 Q. Yeah. That would have been
13 great. I think that the attachment,
14 there's only a bit of it on the next
15 page. The attachment for the job
16 description, Pain Specialty Rep.doc was
17 withheld from production. We'll be
18 calling for it. But I don't have it here
19 to go over it with you. I only have the
20 very -- the three themes to consider,
21 that somebody be a self-starter and be
22 self-motivated, have business and
23 customer insight. Incidentally, it says,
24 "Can they uncover the referral flows in

1 their market?"

2 What does that mean?

3 A. Very simply, that means
4 if -- the referral flows are, in its
5 simplest sense, there are pain
6 specialists in a particular city that are
7 the go-to referral centers from
8 particular doctors. So that helps you
9 isolate who are the specialists in the
10 area that others listen to.

11 Q. And then the next question
12 is, "Can they uncover the treatment
13 algorithms of each practice and be viewed
14 as bringing value?"

15 What does that mean?

16 A. Well, treatment algorithms
17 are important to understand because it
18 overlaps directly with patient flow. So
19 if an orthopedic -- I'll give you an
20 example. If an orthopedic surgeon does
21 a -- does a procedure on somebody, maybe
22 prescribes pain medication upon
23 discharge, but that person has to go to
24 rehab, it's also important to know who

1 that patient's primary care might be in
2 the area so that you can connect the dots
3 in terms of knowing where that patient
4 may be going for follow-up visits.

5 Q. All right. Thank you for
6 that explanation. I'm going to put that
7 aside again.

8 Incidentally, I haven't
9 asked you much about Greg Preston. How
10 did Greg Preston get selected to be the
11 national pain force leader? Did you
12 personally interview him?

13 A. I did personally interview
14 him.

15 Q. What were the qualifications
16 that you recall that led him to get to
17 land that role as head of the pain force
18 team?

19 A. I can't recall the exact --
20 the specific job description. But I
21 worked with Quintiles senior management
22 in describing the kind of person that we
23 felt was important. At that level, it
24 has a dominant -- the dominant criteria

1 would be more how do they interface with
2 senior leaders in the organization across
3 multiple functions, because their job is
4 really to -- their job is oversight of
5 the contract.

6 Q. Where was his office?

7 A. His official office was in
8 Quintiles headquarters in Cary, North
9 Carolina, where I believe he resided.
10 But he did --

11 Q. Did -- I'm sorry. Go ahead.

12 A. But he did have an office in
13 our building, and he was in the -- I
14 can't speak to how often he was in the
15 building. But it was enough to be
16 present. But keep in mind most of the
17 folks in those kinds of roles spend
18 anywhere from 50 to 70 percent of their
19 time on the road meeting with district
20 managers, meeting with reps.

21 Q. Did you fairly consistently
22 check in with him and get updates with
23 him on the accomplishments and efforts of
24 the pain force?

1 A. I think it's fair to say
2 that we were in contact every week, at
3 least once.

4 Q. Did you -- how would you
5 stay in contact? Would you stay in
6 contact by phone, by e-mail?

7 A. Pretty standard to have him
8 included on conference calls regarding
9 performance. And it was fit for
10 purpose -- fit for purpose, whatever was
11 needed to be done. So whether it was
12 phone call or e-mail, we maintained
13 communications.

14 Q. Well, do you recall
15 e-mailing him during the time that he
16 served as your pain force national
17 manager, national director?

18 A. Of course I recall having
19 e-mailed him and called him.

20 Q. Would you have shared
21 metrics over a -- concerning the pain
22 force's outcomes with him via e-mail?

23 A. Very, very high
24 probability -- we talked metrics every

1 week, so whether that was in person or
2 over e-mail, there was going to be some
3 sort of dialogue.

4 Q. How long did you work with
5 him?

6 A. He was selected close to the
7 time of that e-mail that we talked about.
8 And I can't recall whether he was already
9 selected as the national leader or was in
10 final rounds with his own company. And I
11 would have worked with him from the
12 time -- whatever time he was officially
13 named until the time that I left that
14 business.

15 Q. Fair to say that there would
16 be a significant volume of e-mail
17 correspondence during that time with --
18 between you and Greg Preston?

19 A. I can't characterize how
20 much e-mail it was or wasn't.

21 What I -- as the national
22 sales leader, we would most definitely
23 include him on business reviews, which
24 could have been over -- if he was in the

1 building, he would be in person. If he
2 wasn't, he would be calling in. So it
3 could have been a conference call. But
4 there's -- when you go over metrics,
5 there's sales leader, there's analytics,
6 so there's other folks in the discussion
7 as well. So...

8 THE VIDEOGRAPHER: The time
9 is 3:58 p.m. Going off the
10 record.

11 (Brief pause.)

12 THE VIDEOGRAPHER: We are
13 back on the record. The time is
14 3:39 p.m.

15 (Document marked for
16 identification as Exhibit
17 Janssen-Lin-11.)

18 BY MR. JANUSH:

19 Q. I'm going to hand you what
20 has been marked as Lin Exhibit 11. This
21 is the Work Order 6724. Its Bates stamp
22 is JAN-MS-00576727. This is the contract
23 between Quintiles and Janssen, is it not,
24 for the specialty pain force

1 representatives?

2 A. That looks like what it is.

3 Q. Okay. I want to turn to
4 Page 11. And let's see. You are listed
5 as the internal project manager or
6 responsible person to whom the service
7 provider will report. Was that correct?

8 A. Yes.

9 Q. Okay. Now, moving forward
10 to Page 12. Just for the record, year
11 one, this is a two-year sales agreement;
12 is that right?

13 A. That's correct.

14 Q. And so year one, sales force
15 positions, there's a daily rate, an
16 estimated days worked and estimated total
17 fees. And that goes for the sales reps,
18 the 77 sales representatives, the seven
19 district managers, and the one project
20 leader; is that right?

21 A. That looks correct, yeah.

22 Q. And so estimated fees for
23 year one, \$11,957,972.81 for this
24 Quintiles staffed sales force, true?

1 A. Yes.

2 Q. Year two, same numbers, 77
3 sales representatives, seven district
4 managers, one project leader. And we
5 have an increase, and the total estimated
6 fees were \$12,410,699.28; is that right?

7 A. Yeah, that looks right.

8 Q. Do you recall whether you
9 went -- whether Janssen went over these
10 numbers in terms of the -- the total
11 Quintiles sales force cost?

12 A. I don't have any information
13 that would suggest the actual costs in
14 that year.

15 Q. So in total, Janssen agreed
16 to pay an outside company \$24,368,671 to
17 staff a sales force for two years to sell
18 Nucynta; is that right?

19 MR. GALIN: Objection to
20 form.

21 THE WITNESS: Are you adding
22 up the two numbers that are listed
23 here in year one and year two?

24 BY MR. JANUSH:

1 Q. I am.

2 A. Estimates?

3 Q. I am.

4 A. Well, if your math is right,
5 then I would say the estimate for the
6 direct sales force cost from Quintiles
7 was estimated at the time of signing of
8 the contract to be about that number.

9 Q. Do you have any reason to
10 believe that -- that the actual cost
11 didn't match closely with these
12 estimates?

13 A. I have no recollection of
14 any significant deviation from these
15 agreed upon budgets.

16 Q. Did you oversee compensation
17 for the pain sales force?

18 A. I oversaw the crafting of
19 the incentive compensation strategy, but
20 the compensation itself is -- is executed
21 or run through a sales compensation.

22 Q. This was -- these fees that
23 are included in this contract, was
24 this -- was this a base salary and bonus

1 structure estimate, or were these just
2 the base figures?

3 In other words, sales
4 representatives get paid commissions
5 or -- or bonuses based on how many total
6 prescriptions they may sell in a given
7 quarter, right?

8 A. Sure. Is there a particular
9 item that you would like me to look up?

10 Q. There may be. Let's see.
11 Page 13, there's an incentive plan
12 administration at Subparagraph C. It
13 says, "Clients shall pay service provider
14 an amount equal to, 1, the amount of all
15 nonsalary compensation earned by sales
16 force employees in accordance with the
17 terms of the incentive plan or otherwise
18 requested by client, and an amount equal
19 to 9.7 percent of such compensation for
20 service providers employer costs."

21 I understand that this going
22 to the service provider, that's
23 Quintiles, right?

24 A. Yes.

1 MR. GALIN: You are missing
2 the Elmo.

3 MR. JANUSH: Oh, sorry,
4 sorry, thank you.

5 BY MR. JANUSH:

6 Q. That goes to the service
7 provider. But it's referencing all
8 nonsalaried compensation earned by the
9 sales force employees in accordance with
10 the terms of the incentive plan. So was
11 there a separate -- a separate incentive
12 plan or was there an incentive plan that
13 I might be missing?

14 A. My recollection is that
15 there was an incentive plan put in place
16 for the sales force.

17 Q. So, so earlier when I was
18 addressing the -- the \$24 million plus,
19 that's just the base compensation, right?

20 MR. GALIN: Objection to
21 form.

22 THE WITNESS: I -- to be
23 fair, I -- from the costs that we
24 were looking at, or the estimates

1 that we reviewed -- those --

2 BY MR. JANUSH:

3 Q. Well, it breaks it down --

4 A. -- those --

5 Q. -- here.

6 A. -- those do not directly
7 speak to someone's salary. Those were
8 speaking to an average daily rate that
9 the service provider would be paid for
10 the work they provided.

11 Q. Right. In other words,
12 daily rate multiplied by estimated days
13 worked times -- added up to an estimated
14 total days worked, added up to total
15 fees.

16 This is a base salary based
17 on how many days 77 salespeople worked.
18 There's nothing about incentive-based
19 compensation in this, right?

20 A. I don't believe in the
21 numbers we are looking at here involve
22 incentive compensation.

23 Q. Okay. So separate and apart
24 from this agreement, there should be

1 another agreement concerning the
2 Quintiles pain force incentive
3 compensation?

4 MR. GALIN: Objection to
5 form.

6 THE WITNESS: I don't know
7 if there would be a separate
8 agreement to the incentive plan,
9 but my recollection is that there
10 was an incentive plan put in place
11 consistent with that of other
12 Janssen's sales forces.

13 BY MR. JANUSH:

14 Q. Did your sales and marketing
15 team ever target doctors for Nucynta
16 prescriptions because such doctors were
17 high prescribers?

18 A. May I clarify? When you say
19 Nucynta, do you mean Nucynta ER, Nucynta
20 immediate release, or in general the
21 both?

22 Q. We'll -- we'll start with
23 Nucynta ER.

24 A. We targeted -- I think

1 there's a vetting process for how the
2 actual customer targets are derived. The
3 actual number of physicians that wrote
4 long-acting opioids, as I'm speaking to
5 Nucynta ER, was far greater than the
6 number that we could actually reach with
7 the resources we had.

8 But in general, if you asked
9 me for characterizing the targets that we
10 would seek to engage, writers of
11 long-acting opioids, specifically branded
12 ones.

13 Q. Do you recall being involved
14 in communications about setting up a
15 meeting with a high prescribing physician
16 who was very specifically writing
17 prescriptions of your competitor's
18 product and not writing Nucynta ER
19 prescriptions?

20 MR. GALIN: Objection to
21 form.

22 THE WITNESS: During my time
23 as a brand leader, I met with
24 customers when I was out with the

1 sales representatives. I met --
2 when I would go out on a day with
3 a rep. So I would meet with
4 customers as -- as a tagalong to
5 the normal course of their day.

6 Whether or not they fit the
7 exact criteria that you're
8 describing is -- I can't speak yes
9 or no to that with any accuracy.

10 BY MR. JANUSH:

11 Q. So during your tenure as the
12 national sales and marketing director,
13 you -- you actually went and did
14 ride-alongs with sales reps?

15 A. Occasionally. I -- I made
16 it a point to go out once or twice. Most
17 folks in those roles do, to ensure that
18 we didn't lose touch with reality.

19 (Document marked for
20 identification as Exhibit
21 Janssen-Lin-12.)

22 BY MR. JANUSH:

23 Q. I'm going to mark as Exhibit
24 Number 12 an e-mail chain that's Bates

1 number is JAN-MS-00289532.

2 And I'm going to have you
3 turn to the second page of the exhibit
4 ending in 533.

5 And specifically in the
6 middle of the page, Kanitha Burns is
7 writing to Elizabeth Bianciani copying
8 Patricia Yap, David Lin, you, Paul Lowman
9 who we discussed earlier, Ron Kuntz, Lisa
10 Ferguson, Frank DeMiro, and Dominic
11 Lazzaro regarding a doctor named Guang
12 Yang, Opana ER 10 top. Do you see that?

13 A. Yes.

14 Q. I'll actually move this
15 folder. Use this.

16 And Lisa, or Elizabeth
17 Bianciani, I know she goes by -- by Lisa,
18 wrote, "Hi, is anyone able to make it out
19 to Cleveland, Ohio, on Thursday? I am in
20 marketing excellence training on
21 Wednesday through Thursday of this week.
22 Guang Yang has written 558 Opana ER total
23 prescriptions in the past 13 weeks and
24 represents 3,159 long-acting opioid total

1 prescriptions. He has not written any
2 Nucynta ER total prescriptions in the
3 last" -- "in the past 13 weeks. If
4 Thursday does not work, Lisa, could you
5 let me know when you plan on heading out
6 there? Would it be possible to piggyback
7 on your trip."

8 Before I ask a question, I
9 just want to get your confirmation I read
10 this correctly. Yes?

11 A. Yes.

12 Q. Okay. And Kanitha Burns,
13 who is not a sales representative, who is
14 a marketing program director, correct?

15 A. She is in marketing.

16 Q. And she's an executive in
17 marketing, right, fairly high up, just a
18 couple -- a couple slots below Patricia,
19 her -- she reported directly to Patricia
20 Yap, didn't she?

21 A. She did.

22 Q. And Patricia Yap reported
23 directly to you?

24 A. Yes.

1 Q. Okay. So there's David Lin,
2 Patricia Yap, and Kanitha Burns with a
3 number of other employees on that
4 third -- on that third tier. Fair?

5 A. Fair.

6 Q. Okay. "Lisa, I should be
7 able to do it, especially if it's in and
8 out same day. Let's talk tomorrow.
9 Kanitha."

10 Now, I deposed Kanitha Burns
11 not that long ago. I didn't get any
12 testimony from her that she assisted in
13 sales and went out and met with high
14 prescribers of long-acting opioids.

15 How common is that practice
16 to send out a marketing executive from
17 Janssen's headquarters in New Jersey out
18 to Cleveland, Ohio to meet with a high
19 prescriber?

20 MR. GALIN: Objection to
21 form.

22 THE WITNESS: Well, first
23 let's talk about the role. So I
24 would say Kanitha and others like

1 Kanitha are definitely people --
2 those are -- those are roles that
3 are primarily based on marketing.
4 But marketing and sales have a
5 very close collaboration.

6 And I would characterize it
7 as, it is true that occasionally
8 someone from home office may visit
9 a customer for the purpose of
10 learning about the customer's
11 practice, their -- the area,
12 hearing about things like managed
13 care.

14 BY MR. JANUSH:

15 Q. He hadn't written a
16 prescription in 13 weeks. He wasn't
17 really a customer right then, right?

18 A. No.

19 Q. In fact, it's because he was
20 writing a competitor's -- script for --
21 prescriptions for Opana ER that he was
22 specifically targeted for a visit; isn't
23 that right?

24 A. Based on the

1 characterization in this e-mail chain,
2 that's exactly why you'd want to visit
3 the customer, is to learn why they do
4 what they do.

5 Q. And to convince them to
6 consider writing for Nucynta ER, right?

7 A. Absolutely. The end game is
8 to drive awareness of your product with a
9 customer that is using long-acting
10 opioids.

11 Q. A doctor -- let me ask you a
12 different question.

13 When Lisa or Elizabeth
14 Bianciani is reporting out that, "Guang
15 Yang has written 558 Opana ER
16 prescriptions in the past 13 weeks and
17 represents 3,159 long-acting opioid total
18 prescriptions," is the 3,159 an annual
19 metric? Like, how is that being used, if
20 you know?

21 A. I -- there's no data source
22 here to say what time period it is, so I
23 can only -- typically, those numbers are
24 read quarterly or annually.

1 Q. And the subject is Opana is
2 Guang Yang -- Guang Yang Opana ER 10 top.

3 Is that referring to the
4 fact that Guang Yang is a top 10 Opana ER
5 prescriber?

6 A. I can't verify that that
7 is -- that that doctor is a top 10
8 prescriber of Opana ER. But I
9 acknowledge that the concept would be
10 something that would potentially be
11 discussed.

12 Q. When you say the concept,
13 the concept in this subject -- this
14 subject line --

15 A. Yes.

16 Q. -- the Opana ER ten top?

17 A. Not specific to Opana ER,
18 but a customer who has adopted branded
19 long-acting opioids is really in the
20 sweet spot of where all the competitors
21 want to compete.

22 Q. They're considered -- in
23 decile terms, what would -- what would a
24 doctor like this be considered?

1 A. I don't know where they
2 would be considered in the decile of a
3 long-acting opioid prescriber. But the
4 general thesis is that if they are
5 willing to consider branded products,
6 then they might not be as -- they might
7 not be as wed to generic only.

8 Q. I mean, assuming that Dr.
9 Guang Yang worked five days a week in an
10 office practice and wasn't working
11 weekends, and worked for 13 weeks, we're
12 talking about 65 days of writing
13 prescriptions and it amounts to 8.5 Opana
14 ER prescriptions per day. That's a lot
15 of pain -- opioid pain prescriptions
16 written in one day, isn't it?

17 MR. GALIN: Objection to
18 form.

19 MS. NAKAMURA: Objection to
20 form.

21 THE WITNESS: I can't -- I
22 can't speak to where that ranks
23 because we're giving a lot of
24 hypotheticals about the days

1 worked, the number of patients
2 seen. I think it's unfair to
3 categorize that level of
4 prescribing for any one
5 prescriber.

6 THE COURT REPORTER: Could
7 you tell me who was objecting?
8 Can you say your name?

9 MS. NAKAMURA: This is Angel
10 Nakamura of Arnold & Porter for
11 Endo.

12 THE COURT REPORTER: Thank
13 you.

14 MR. GALIN: Mr. Janush, are
15 you done with this?

16 MR. JANUSH: I'm going to
17 move on from this topic.

18 MR. GALIN: Okay. I wanted
19 to wait until you were done just
20 to make one point, which is, for
21 the record, there appears on it
22 some highlighting in the middle of
23 it. My understanding is it was
24 not produced with the

1 highlighting, so just for the
2 actual record -- I don't know
3 where the highlighting came on. I
4 just want the exhibit to be
5 accurate.

6 MR. JANUSH: This actually
7 was produced, we believe, just as
8 you're seeing it. If not, look in
9 the native. Not the image. Look
10 in the native. And if we're
11 wrong, we didn't highlight it. So
12 I think you have to look at the
13 native.

14 MR. GALIN: Not making an
15 issue of it now. We'll just
16 figure it out.

17 MR. JANUSH: Understand
18 this. I will always do the right
19 thing and work with you always.
20 So if its native production is not
21 highlighted, we will make sure
22 that we fix it.

23 MS. WINCKEL: It's not.

24 MR. JANUSH: It's not?

1 Okay. I didn't do it.

2 MR. GALIN: I'm not
3 suggesting anything deceptive.

4 MR. JANUSH: We will
5 absolutely swap out this exhibit
6 for an unhighlighted version.

7 MR. GALIN: We've been
8 going, other than our little
9 15-minute break -- or second
10 break, we've been going for about
11 an hour and 25 or so minutes. I
12 don't know how others feel. I'm
13 okay. The witness, how do you
14 feel? Should we take a break now?
15 Any other in the room as well?
16 There's others in the room as
17 well.

18 MR. ALLEGAERT: You guys
19 decide what you want to do. The
20 court reporter is the most
21 important person.

22 THE COURT REPORTER: I'm
23 fine. Whatever you guys want to
24 do.

1 THE WITNESS: I can go
2 another 15 minutes before a bio
3 break.

4 BY MR. JANUSH:

5 Q. Okay: All right. I'm going
6 to hand you what's been marked as Lin
7 Exhibit 13.

8 (Document marked for
9 identification as Exhibit
10 Janssen-Lin-13.)

11 BY MR. JANUSH:

12 Q. This concerns an e-mail, a
13 parent e-mail, and an attachment. The
14 parent e-mail is JAN-MS-0066055 -- 0588.
15 The attachment is 00660589. Again, Lin
16 Exhibit 13.

17 The parent e-mail is from a
18 Stephanie Melo to Johnette Johnson cc'g
19 Frank DeMiro, you, Mr. Lin, and Patricia
20 Yap.

21 Do you see that on the first
22 page?

23 A. Mm-hmm.

24 Q. And it's addressing an

1 extended team meeting that is soon to
2 occur, a proposed agenda. You're listed
3 as providing the pain sales force update.
4 And then we go into the extended team
5 meeting slide deck. That is the
6 attachment.

7 So first, second slide, just
8 as in the e-mail, you are listed as
9 providing a pain sales force update; is
10 that right?

11 A. Yes.

12 Q. Okay. And then I'm going to
13 draw your attention to Slide 5 where the
14 presentation addresses, "Generate data on
15 comparative" -- effectiveness --
16 effective -- efficacy -- sorry,
17 "efficiency, and abuse."

18 What was being sought from
19 Janssen's perspective in addressing
20 efficiency and abuse?

21 A. So in the context of this
22 document, I want to clarify, that the
23 grayed-out box, because it is grayed out,
24 this is the responsibility of the medical

1 affairs health economics team. So
2 typically we call these integrated
3 strategies, so you can see on one page
4 what's being -- what's being worked on.

5 So the specifics of what
6 usually comes out of these, or why
7 there're topics that are on there is they
8 are probably -- they are usually
9 referencing key topics that are asked by
10 healthcare providers, other key opinion
11 leaders -- it could be a payer. And
12 those top issues that are raised would be
13 captured by medical affairs, and they
14 would be placed into a strategy document
15 to say we should -- in order to satisfy
16 inquiries from our outside stakeholders
17 we should try to generate data on these
18 topics.

19 Whether or not there was
20 ever budget specifically for every topic
21 that's listed here, is not clear. But
22 that was the stated intent.

23 Q. Okay. And at the top you
24 are addressing some key business

1 questions.

2 A. Yep.

3 Q. What is the potential impact
4 of generic Opana ER and OxyContin
5 entrants in long-acting opioid market?

6 What's the answer to that
7 within this slide, if there is one?

8 A. Well, there's not a direct
9 correlation between a key question. They
10 are meant to be thought provoking in
11 terms of the general conditions in that
12 competitive environment.

13 So I -- I would say most
14 likely the -- the middle column there, in
15 terms of access and value proposition,
16 would probably, in part, evolved from
17 some of those questions that you just
18 mentioned in that third box.

19 Q. So what does it mean to
20 enhance the integration of access
21 message?

22 A. Well, looking back to the
23 discussion we had earlier, one potential
24 example of integration of access message

1 is, if the brand received, I'll use for
2 example maybe a Tier 2 status on a
3 particular health plan that we mentioned
4 as the parent national plan, but that the
5 regional children plans weren't
6 necessarily adopting that same -- that
7 same tier placement, it would be
8 incumbent upon, not only our national
9 account directors who deal with managed
10 care plans, but also our sales leaders,
11 to make sure that they actively engage
12 those local plans and say just wanted to
13 clarify that your parent plan has us on
14 Tier 2 to be used after let's say a
15 generic and at a co-pay of X dollars. We
16 want to make sure that you're aware that
17 that's the coverage of your national
18 plan.

19 That -- when that doesn't
20 happen correctly, then there are -- it
21 can lead to customer confusion.

22 Q. I'm going to move forward to
23 Slide 7. This is just the org chart
24 showing the Janssen pain organization

1 resides within the CNS business unit.

2 CNS stands for what

3 incidentally?

4 A. Central nervous system.

5 Q. Okay. And this is the --

6 the Michael Yang you talked about this

7 morning that was the individual who would

8 have reviewed you in your role when you

9 were, I believe, both the national

10 marketing director and national sales

11 director; is that right?

12 A. That's right.

13 Q. The next slide at Page 8.

14 This is just addressing the pain force

15 that we were discussing earlier. And on

16 the right side, it says, "Focus coverage

17 of high prescribers within targeted

18 markets." And that's what you were

19 speaking to earlier, isn't it, regarding

20 the territories where there are a

21 concentration of opioid prescribers,

22 physicians prescribing long-acting

23 opioids?

24 MR. GALIN: Objection to

1 form.

2 BY MR. JANUSH:

3 Q. Is that right?

4 A. The -- the focus -- the
5 reason why this is here, stated here, I'm
6 going back a number of years, but it was
7 important at the time to make sure that
8 the extended team, which was
9 cross-functional partners, would have
10 confidence that the representatives that
11 were hired were hired to be in the most
12 important markets.

13 So coverage of the folks who
14 wrote long-acting and short-acting
15 opioids, with a focus on branded.

16 Q. Okay. And the next slide at
17 Slide 9 is a map for the pain specialist
18 group. This is for your pain force for
19 2013; is that right?

20 A. Yes, that's --

21 Q. And it's color-coded. And
22 it's color-coded in seven colors which
23 line up in the key at the bottom to the
24 different regions or districts that were

1 carved out for the pain specialty Nucynta
2 pain force group; is that right?

3 A. That's right.

4 Q. Okay. So earlier I talked
5 about the difference between sales reps
6 detailing across the country versus in
7 targeted locations, right?

8 A. Yes.

9 Q. This map, to use a Janssen
10 line from an earlier PowerPoint, a
11 picture is worth a thousand words, right?

12 A. Yes.

13 Q. This map identifies the --
14 the areas of greater intensity of focus
15 where Janssen was dedicating its Nucynta
16 pain force sales representatives; is that
17 right?

18 A. That's correct. This is
19 the -- this is meant to depict the
20 deployment of the sales team.

21 Q. Okay. If the colors of each
22 region are not observed in any of the
23 states that are listed, that are set
24 forth as blank or white, does that mean

1 that Janssen did not send sales reps into
2 those territories to detail Nucynta?

3 A. That is -- yes, that's
4 right.

5 Q. Was one of the goals,
6 therefore, to target the territories, the
7 regions or districts, however, whatever
8 is the appropriate term used, that
9 historically had the higher volume of
10 long-acting and short-acting opioid
11 prescriptions?

12 MR. GALIN: Objection to
13 form.

14 THE WITNESS: I think it's
15 fair to say that to place a rep in
16 a particular geography, two things
17 were taken into consideration.
18 The overall size of the geography
19 and making sure you had within a
20 rough concentric circle, that
21 would allow a rep to be productive
22 with a number of customers that
23 were deemed to be good potential
24 customers -- a number of physician

1 customers that were deemed to be
2 good Nucynta ER or Nucynta target
3 customers.

4 BY MR. JANUSH:

5 Q. And moving on to the next
6 slide. Fair to say that in the past, in
7 2012, in fourth quarter 2012, Nucynta
8 targets totaled approximately 46,000
9 targets, right?

10 MR. GALIN: Objection to
11 form.

12 THE WITNESS: According to
13 the -- the document that I'm
14 looking at, it does look like
15 there was approximately 46,000
16 targets in the fourth quarter of
17 2012.

18 BY MR. JANUSH:

19 Q. And the major change with
20 this pain force transition, with this
21 Quintiles contract sales force, is that
22 in first quarter 2013, the sales force
23 would -- would look at three different
24 groups of customers, one of which is

1 greyed out. The first group is Nucynta
2 targets transitioning to pain team, and
3 that's approximately 7,000 healthcare
4 practitioners; is that right?

5 A. Yes.

6 Q. And the second is Nucynta
7 opt-in targets, and that's listed as
8 being approximately 6,000 targets, right?

9 MR. GALIN: Object to form.

10 BY MR. JANUSH:

11 Q. What is a --

12 THE COURT REPORTER: I need
13 an answer.

14 MR. JANUSH: Oh, thank you.
15 Sorry.

16 BY MR. JANUSH:

17 Q. That's -- that's Nucynta
18 opt-in targets. That's at approximately
19 6,000 targets; is that right?

20 A. Yes. The label says 6,000.

21 Q. What's a Nucynta opt-in
22 target?

23 A. I don't recall directly
24 right now what an opt-in target was. I'm

1 going to venture to guess only that it's
2 a customer that expressed interest in
3 Nucynta or that might have been flagged
4 that -- from a prior sales team that they
5 were -- they thought they were going to
6 be able to make some constructive inroads
7 with that customer.

8 Q. And then the greyed box is
9 Nucynta nontargets at 23,000. Does this
10 mean these are the -- these are the
11 doctors that this new sales force will
12 not be targeting?

13 A. I can't be -- I can't be
14 certain as to what this meant. This
15 is -- this is quite -- quite a ways back.

16 But I would venture to say
17 that just given the placement and the
18 hierarchy, it's the least important of
19 the targets that are being discussed in
20 this meeting.

21 Q. And in this meeting, there's
22 also a discussion on multiple delivery
23 vehicle for peer-to-peer speaker programs
24 at Slide 20. Do you see that?

1 A. Yes.

2 Q. So is it the case that
3 Janssen offered all three of these
4 different types of peer-to-peer speaker
5 programs, the first being live programs,
6 the second being virtual programs, and
7 the third being these pull-through
8 vehicles with speaker news channels and
9 attendee news channel and target news
10 channel?

11 A. Yes. This appears to be the
12 basic format of the peer-to-peer program.

13 Q. And in the virtual programs,
14 those are where a physician can go on
15 meeting direct and, through a website,
16 see a virtual program. Is it -- is it a
17 scheduled program or something that's
18 pre-recorded and available at any time?

19 A. I can't recall whether it
20 was pre-recorded or whether it was
21 scheduled.

22 If I had to guess, it could
23 have been a mix of both.

24 Q. And the third category,

1 pull-through vehicles, can you tell us
2 what speakers news channel is and
3 attendee news channel and target news
4 channel, one by one?

5 A. You know, I've never watched
6 one of these particular programs. So I
7 can only guess based on the labeling
8 that's on it, exactly what they were
9 intended for.

10 But in general, they're used
11 as follow-up. That's why we use the term
12 pull-through. So if someone attended a
13 program, and they offered their e-mail
14 address and that they wanted to receive
15 an update, if there ever was one, if
16 there was a worthy update, they could be
17 e-mailed a link that said, "If you'd like
18 to learn more about what we covered at
19 the last speaker program, you can click
20 here and hear more."

21 Q. So is the naming designation
22 "pull-through vehicles" used to address
23 pulling a doctor, you know, over the line
24 into Nucynta's product line?

1 A. I think -- in fairness, I
2 think these marketing programs are
3 designed to capture someone's attention,
4 educate them, and then give them all the
5 opportunity to learn more. So that's how
6 we want to characterize it. Pull-through
7 is make sure they have another avenue to
8 ask questions or get more information.

9 MR. JANUSH: Let's go off
10 the record with a break.

11 THE VIDEOGRAPHER: Stand by,
12 please. The time is 4:19 p.m.
13 Off the record.

14 (Short break.)

15 THE VIDEOGRAPHER: We are
16 back on the record. The time is
17 4:38 p.m.

18 BY MR. JANUSH:

19 Q. Mr. Lin, I'm going to go
20 back to Exhibit 13, because I didn't
21 question you about one of the maps that
22 was on it. So I questioned you about
23 the --

24 THE VIDEOGRAPHER: Your

1 microphone. It's right there.

2 BY MR. JANUSH:

3 Q. On Exhibit 13 at Slide 30,
4 Page 30, is a different map. It's
5 more -- it's the central district here,
6 and it's coded in multiple different
7 colors, whereas on the national map it
8 seemed like this area had one or two
9 colors.

10 First of all, just to
11 confirm, I see Columbus, Ohio, is in
12 green. Youngstown, Ohio, is in green.
13 Toledo, Ohio, is in yellow. Cincinnati,
14 Ohio, is in pink.

15 First question is, if you
16 know, why -- why were the -- why was Ohio
17 and some of these other territories
18 broken up by multiple colors on this map?

19 A. This map, it looks like each
20 color is representing a specific sales
21 territory.

22 Q. Okay. So it says pain
23 specialist 2013. Pain specialist 2013,
24 Page 9. Check it out on the screen. I'm

1 just going back and forth between the
2 two.

3 And so orange would have
4 covered all of central on the big map.
5 And that's one territory, correct, or
6 one -- one district or region?

7 A. Region or district.

8 Q. Okay. And so within regions
9 or districts there were multiple
10 territories; is that right?

11 A. That's right.

12 Q. It may be the case -- so in
13 looking at Ohio, it looks like Cleveland
14 is a different green than Columbus, and
15 then there's the yellow for Toledo and
16 Cincinnati. So is it fair to say that as
17 it concerned Ohio, within the central
18 district or territory, there were --
19 district or region, there were four
20 sub-territories; is that right?

21 A. I would describe these to be
22 four territories. And yeah, every color
23 on here -- it's got a number in the
24 key -- is probably a territory.

1 Q. Okay. And again, Ohio falls
2 within the central district, right, going
3 back to the screen?

4 A. Yes.

5 Q. And the central district is
6 one of the districts that was one of the
7 seven targeted districts for the new pain
8 force, the new Nucynta contract sales
9 organization pain force in 2013; is that
10 right?

11 A. That's right.

12 Q. Okay.

13 (Document marked for
14 identification as Exhibit
15 Janssen-Lin-14.)

16 BY MR. JANUSH:

17 Q. I'm going to hand you what's
18 been marked JAN-00010363. That is marked
19 as Exhibit 14. And this is a slide deck
20 titled "Nucynta ER Launch Readiness,
21 Launch Governance Review," dated April 7,
22 2011. And with this, I'm going to turn
23 your attention to Slide 12. And I'm
24 going to key in on -- at the top,

1 "Utilizing peer-to-peer to accelerate
2 impact. National train top 25 KOL
3 clinical educators."

4 Is this referring to train
5 the top 25 key opinion leaders and
6 clinical educators to assist in
7 peer-to-peer communications?

8 A. Yes, I believe so.

9 Q. And then at the regional
10 level, it's addressing, "Regional live
11 programs targeting Nucynta
12 launch-friendly states, which are listed
13 to be Ohio, Florida, California, Texas,
14 and New York." Is that right?

15 A. That's what that says, yes.

16 Q. What does it mean to -- for
17 Ohio, as an example, to be listed as a
18 Nucynta launch-friendly state?

19 A. The exact definition of a
20 launch-friendly state is not -- I don't
21 want to speculate as to what that means.
22 But in general, the launch of Nucynta ER,
23 one of the key considerations for the
24 launch of Nucynta ER was that if you had

1 prescribers who already have adopted
2 Nucynta, one of the first places that a
3 sales team would want to go to is
4 somebody who's already tried Nucynta as
5 they're introducing Nucynta ER.

6 Q. But we are not talking about
7 individual prescribers on this slide.
8 It's more specifically or more broadly
9 talking about launch-friendly states. So
10 is this taking into account that Ohio,
11 Florida, California, Texas and New York
12 are states where there are already a fair
13 amount of Nucynta prescribers, and,
14 therefore, Nucynta ER already has a
15 platform from which to spring off of
16 Nucynta IR?

17 A. I'm -- it's unclear from
18 this deck, but in terms of markets, I
19 would -- I'm going to guess that these
20 were places where Nucynta uptake might
21 have been healthier than other markets in
22 the country, and those would be the
23 places that the team would want to start
24 with Nucynta ER.

1 Q. Okay. So since I don't want
2 you to guess, I'm going to go back to the
3 last exhibit, Exhibit 13. We're going to
4 go back to that Slide 9, the national
5 map, and confirm whether your guess was
6 correct.

7 So I'm looking at
8 California, Texas -- some coloration --
9 Ohio, New York, and Florida. And all of
10 the states that I just listed are states
11 where -- that fall within the seven
12 regions that the new pain force was
13 dedicated to; is that right?

14 A. I would agree there's a
15 correlation between what's written on
16 Slide 12 of the exhibit we're looking at,
17 which is prelaunch of Nucynta ER, and
18 also the field deployment in 2013.

19 There is a correlation in
20 that some of the states that are
21 mentioned on one slide also appear to be
22 on the deployment map of 2013.

23 Q. Okay. And when you say some
24 of the states that are listed on Page 12

1 of Exhibit 14 --

2 A. Yeah.

3 Q. -- it's actually all of the
4 states listed. I'm going to circle.
5 Ohio, Florida, California, Texas, and New
6 York, all appear as a correlation within
7 the seven districts?

8 MR. GALIN: Objection to
9 form.

10 BY MR. JANUSH:

11 Q. Isn't that right?

12 MR. GALIN: Objection to
13 form.

14 THE WITNESS: Yeah. I want
15 to clarify. So I'm sorry, I was
16 looking at Slide 9 of the previous
17 exhibit --

18 BY MR. JANUSH:

19 Q. Fair.

20 A. -- to say that there are
21 other states that are covered, but not
22 listed here. But there is an overlap.
23 I'm agreeing.

24 (Document marked for

1 identification as Exhibit

2 Janssen-Lin-15.)

3 BY MR. JANUSH:

4 Q. I'm going to hand you a
5 document that I'm marking Lin Exhibit 15.
6 This is another instance of a parent
7 e-mail and attachment. The parent e-mail
8 is JAN-MS-01049657. The attachment is
9 JAN-MS-1049659.

10 The e-mail is from you and
11 it's to a group of people, addressing --
12 we're going back in time now to 2010. So
13 this would be Nucynta IR, original
14 Nucynta days, right? And it's the
15 PriCara pain incentive compensation plan
16 that's being attached.

17 So my first question is,
18 this is one of the few documents that I
19 found associated with your name that
20 addresses PriCara as opposed to Janssen.
21 Tell us about PriCara's involvement with
22 Nucynta.

23 A. So this is -- e-mail is
24 dated January 20th, 2010. So I'm about

1 20 calendar days into my role. PriCara
2 was the name of the organization that
3 sold Levaquin, which is an
4 anti-infective, AcipHex, GI drug, and
5 then launched Nucynta. PriCara was the
6 name of the operating unit. So the
7 pain -- I'm sorry, sales force was just
8 generally called PriCara.

9 Q. So is that why I see in an
10 e-mail parenthetical, or bracketed, OMP,
11 is that Ortho-McNeil PriCara U.S.?

12 A. No.

13 Q. No?

14 A. I think --

15 Q. Or is that Ortho-McNeil
16 Pharmaceutical U.S.?

17 A. I think it's Ortho-McNeil
18 Pharmaceutical, but I also would
19 recommend or suggest that those suffixes,
20 if you will, have very little to do often
21 with the exact business unit. They're
22 just IT -- different servers.

23 Q. Okay. So I'm going to jump
24 forward as quickly as I can. This is

1 just -- I just wanted to provide the
2 parent e-mail to underscore that you were
3 the person who was attaching the
4 attachment that was called the final
5 PowerPoint "2010 PriCara pain incentive
6 plan cycle one."

7 And I'm going to jump
8 forward to Slide 9 within the PowerPoint.

9 Starting with the first
10 arrow, "Pay per prescription above
11 baseline. Great earning opportunity.
12 You are paid for every prescription above
13 your baseline."

14 Tell us what this means in
15 short.

16 A. Well, I think it's -- once
17 you determine what the baseline is,
18 someone has to cross over that baseline
19 in order to get paid incrementally for
20 every prescription.

21 Q. And there was also a volume
22 leaders bonus for the top two territories
23 with total Nucynta volume earned more
24 than the rest; is that right?

1 A. That appears to be a
2 highlight for the plan, yes.

3 Q. Okay. I want to move
4 forward two slides to Number 11.

5 And, "Goal: Grow number of
6 prescriptions per prescriber." And above
7 that -- and that's for persistency.

8 So is persistency referring
9 to frequency of visits and growing
10 prescriptions per prescriber through
11 being persistent as a sales -- sales rep?

12 A. I think the -- what's
13 alluded to here, because the audience is
14 a sales rep, it's not about how many
15 visits you make. It's about the fact
16 that there's a need to cultivate new
17 customers. And in marketing speak, you
18 want the customer to not just try
19 something. You want them to try it and
20 think it can be part of their practice.
21 So the number of prescriptions per
22 prescriber would be one of those very
23 subtle intangible markers of, they've
24 made it part of their decision choice as

1 opposed to just trying it once.

2 Q. So that would speak to what
3 we were talking about earlier regarding
4 that -- that doctor in Cleveland, Ohio,
5 who was a high Opana ER prescriber.
6 Getting someone like that who -- who
7 isn't just trying it once, but is
8 committed to prescribing your branded
9 product; is that right?

10 A. I think that's --

11 MR. GALIN: Objection to
12 form.

13 MS. NAKAMURA: Objection to
14 form.

15 THE WITNESS: In general,
16 when you cultivate a customer,
17 you -- you want to have them try
18 something, and assuming they see
19 the clinical results based on the
20 product profile that you have
21 educated them on, you want them to
22 make it part of their solution
23 set.

24 And in this case, if a

1 doctor is going to write a
2 short-acting opioid, the desire or
3 the objective for the rep is to
4 make sure that Nucynta is
5 considered part of those -- like a
6 legitimate choice in that doctor's
7 suite of options.

8 BY MR. JANUSH:

9 Q. And then the next slide,
10 focusing on "sell more, earn more,
11 earnings are uncapped. Targeted earnings
12 22,000 per annum."

13 Is this referring to that
14 the sales reps targeted bonus earnings
15 should be \$22,000 per year?

16 A. That is not a -- my
17 recollection of these numbers is that a
18 \$22,000 figure is not representative of a
19 promise.

20 Q. Oh, I understand that.

21 A. It probably, if history
22 serves me correctly, is that that is a
23 budgeted amount per representative if
24 they hit baseline of everything. So

1 that'll be the, you know, if you hit
2 everything to objective, that's your
3 starting pool.

4 Q. And here, you were
5 introducing a bonus plan where, if you go
6 above baseline, a sales rep would get
7 paid per prescription; is that right?

8 A. That's what it says, yes.

9 Q. And the more prescriptions
10 you generate, the larger, in big orange
11 bold letters, your reward; is that right?

12 A. I agree that's what -- what
13 it says.

14 Q. Okay. And there's a great
15 image here. More of this, written
16 prescriptions, equals more cash. Is that
17 what that's showing?

18 A. That indeed is the visual.

19 Q. Okay. And in the very next
20 slide, it's showing a sales
21 representative's pay per total
22 prescription rates. And, if I understand
23 this correctly, it looks like, starting
24 at Prescription 1 and running through

1 Prescription 49, a sales rep would get
2 \$20 per prescription; is that right?

3 A. According --

4 Q. I'm at Slide 13.

5 A. Yeah, according to what I
6 see here, and I'm going to clarify, at
7 least my understanding is that above
8 baseline -- everything above
9 baseline's -- the first prescription to
10 the 49th prescription following baseline,
11 the pay per prescription rate is \$20.

12 Q. Okay. Here, however, it
13 doesn't -- it's not addressing a
14 baseline. This compensation plan seems
15 to be saying get paid for every
16 prescription -- or no, I apologize.

17 On Slide 12 I see above
18 baseline pay per prescription, with pay
19 per prescription tiers.

20 So in other words, if -- if
21 a sales rep has a specific baseline
22 target and they exceed their core that
23 they are supposed to sell or have
24 prescribed within their region, then when

1 they go above that number, every
2 prescription between 1 and 49 they get
3 paid an extra \$20; is that right?

4 And then from 50 to 99 they
5 get paid an extra \$25; is that right?

6 A. That's -- that's right.

7 Q. And then from 100 to 149,
8 they get paid an extra \$30 per
9 prescription, right?

10 And then from 150 to 249,
11 they get paid an extra \$45 per
12 prescription; is that right?

13 And then starting at
14 Prescription Number 250 above baseline
15 and ending nowhere because it's uncapped,
16 they would get \$60 per every additional
17 prescription that a doctor writes; is
18 that correct?

19 A. That's correct, according to
20 the table.

21 Q. Okay. And the next page,
22 Slide 14 addresses you are paid on all
23 prescribers in all zip codes within your
24 territory total DIRT. Do you see that?

1 A. Yes.

2 Q. And it says, "Based on IMS
3 best address and recent call activity."

4 What does that mean, the
5 "based on IMS address" -- "best address
6 and recent call activity"?

7 A. I am not an expert in the
8 call planning -- call targeting area.
9 But IMS is the database that's accessed
10 to determine the -- the existence of a
11 target, the address, the doctor's name,
12 the medical license number.

13 My guess, based on what's
14 written here, is that best address has
15 something to do with the fact that
16 sometimes there are doctors. It was
17 often the case that doctors had an office
18 in a hospital in one district and maybe
19 they had a private practice office in
20 another zip code. And so verifying their
21 address was often a consideration,
22 particularly with the targets that were
23 being called on for Nucynta.

24 And the recent call activity

1 has to do with whatever the most recent
2 database showed as the -- if the doctor
3 was in your zip code.

4 Q. Okay. And the next slide
5 addresses additional incentive awards for
6 sales reps, particularly the president's
7 award, rewards the best of the best, an
8 exciting award opportunity for the best
9 performers.

10 And it looks like there's a
11 picture of a beach at oceanfront, a
12 resort at poolside, and a ski resort or a
13 snowy mountain. Do you see those images
14 at Page 15?

15 A. Yes, I do.

16 Q. Okay. Did Janssen reward
17 the best of the best sales
18 representatives with beach vacations or
19 vacations of the like depicted in these
20 pictures?

21 A. I can't speak to what venues
22 the best of the best were treated to.

23 Q. Can you speak to whether
24 they were treated to venues though?

1 A. Historically, the top very
2 small percentage, and I -- I don't know
3 the number, it's a handful of people,
4 would be recognized, and that's a
5 cumulative across all product portfolios.

6 They -- the top bunch would
7 be recognized in something usually akin
8 to the president's award.

9 What constituted that
10 president's award at one point did
11 involve a trip, a reward trip. And --
12 and I just can't speak to whether or not
13 there was one that happened on a beach or
14 on a mountain.

15 Q. Right. But it would have
16 been a trip to some destination?

17 A. Yes. The top sales force,
18 the top performers of every sales force
19 in the organization would be together
20 typically in a rewards trip.

21 Q. An all-expenses-paid
22 vacation or getaway?

23 A. It's an all-expense-paid for
24 the person, yeah. It's -- it's like --

1 that's part of why it's called a reward
2 trip.

3 Q. Okay. And then the
4 AwardperQs underneath that. What is
5 AwardperQs?

6 A. My -- my recollection was
7 award -- I think it was called
8 AwardperQs.

9 Q. Oh.

10 A. And they were just -- when
11 someone didn't necessarily -- if -- I
12 think you could -- there were perk points
13 or some sort of reward points that
14 correlated with some unit of measure.
15 And if someone chose, instead of taking a
16 trip, they could redeem their points for
17 something else, very akin to service
18 anniversary gifts.

19 Q. So they could receive their
20 AwardperQs for merchandise, and it says
21 "tremendous travel"?

22 A. It does say "tremendous
23 travel."

24 Q. And one of the things that

1 are listed here is -- appears to be like
2 a designer purse or handbag; is that
3 right?

4 A. It looks like a bag of some
5 sort.

6 Q. And another is a laptop; is
7 that right?

8 A. That looks like a laptop.

9 Q. And another perk is a TAG
10 Heuer watch.

11 Do you see that?

12 A. I see a watch. I can't
13 speak to the brand.

14 Q. And another is a set of golf
15 clubs; is that right?

16 A. Yes.

17 Q. Okay. We're going to go
18 over one more slide before we move off
19 this exhibit. The slide is "Earnings
20 examples." And it brings up what you
21 were addressing earlier about earnings
22 over baseline, prescriptions written over
23 baseline. I'm at Slide 22.

24 And this is giving a

1 hypothetical example that if someone's
2 baseline volume is 199, but they got
3 doctors to write 490 total prescriptions,
4 they would be at 291 prescriptions total
5 over baseline.

6 Do you see that?

7 A. Yes.

8 Q. And so with Tier 1, 2, 3, 4,
9 and 5, all being impacted because they
10 went over that 200, and because they are
11 at 291 over baseline, it's showing how
12 the math would work out for the first 49
13 prescriptions over baseline at \$20; the
14 second, 50 at \$25; the third tier, 50
15 prescriptions at \$30; and so on, to
16 quarterly earnings of \$10,750 in bonus
17 earnings for one quarter.

18 Do you see that?

19 A. Yes.

20 Q. So was this a better plan in
21 terms of opportunities afforded in 2010
22 to Nucynta sales reps than what existed
23 in 2009?

24 MR. GALIN: Objection to

1 form.

2 THE WITNESS: I don't -- I
3 can't speak to -- well, two
4 things. One is, I don't know the
5 2009 incentive compensation plan
6 for Nucynta.

7 BY MR. JANUSH:

8 Q. Okay.

9 A. That's one.

10 Number two is I'm not an
11 expert in incentive compensation. But
12 what I do recall is that the examples
13 that are portrayed usually give you --
14 they give you an example of how the
15 calculation works, but they are designed
16 to motivate. And because they are
17 designed to motivate, it's a very -- when
18 they're modeled, a very small number --
19 just from a budgeting perspective, a very
20 small number of representatives would
21 actually have the feasibility to achieve
22 this model.

23 Q. Focusing on what you said,
24 it's designed to motivate sales

1 representatives to get doctors to write
2 Nucynta prescriptions --

3 A. Yes.

4 Q. -- to increase the sales
5 rep's bonus earnings, correct?

6 A. Correct.

7 (Document marked for
8 identification as Exhibit
9 Janssen-Lin-16.)

10 BY MR. JANUSH:

11 Q. I'm going to hand you what
12 I'm marking as Lin Exhibit 16. This is
13 another example of three documents
14 combined for one exhibit. It is a parent
15 e-mail at JAN-MS-02069472 with an
16 attachment at JAN-MS-02069476, and a
17 second attachment at JAN-MS-02069473.

18 I'll hand you Exhibit 16.

19 MR. JANUSH: And counsel.

20 BY MR. JANUSH:

21 Q. This is an e-mail from you
22 to members, I believe, of the marketing
23 team regarding a -- it's sent January 18,
24 2013. And it's concerning KOLs attending

1 the national sales meeting.

2 Do you see that?

3 A. Yes, I do.

4 Q. Okay. And here we're going
5 back to the subject of launching a new
6 specialty pain force that we
7 affectionately call them the pain force.
8 And at this point in time, it seems that
9 you are confirming the team is hired and
10 is currently in process with home study
11 and will enter the market in the next two
12 weeks.

13 Earlier we spoke about not
14 pinning down exactly when they were being
15 put into -- the sales force integrated.
16 So this seems to indicate that somewhere
17 between the end of January and beginning
18 of February of 2013, the new pain force
19 was entering the game; is that right?

20 A. I think, yes, broadly
21 speaking, that's correct.

22 Q. And you are addressing,
23 towards the bottom of this e-mail, "While
24 the pain force is an experienced group of

1 sales professionals, we intend to
2 thoroughly prepare them to deliver
3 maximum value and impact to the pain
4 community. To that end, we will be
5 conducting one and a half days of KOL
6 immersion training at upcoming pain force
7 national sales meeting."

8 Do you see that?

9 A. I do.

10 Q. Do you recall being part of
11 leading a KOL immersion training for the
12 new pain force at the pain force national
13 sales meeting?

14 A. I recall being at the
15 meeting. This particular national sales
16 meeting, I kicked off the national sales
17 meeting. I did not personally set up the
18 immersion training. But I do know that
19 it took place.

20 Q. Okay. "We have" -- and it
21 continues to say, quote -- you continue
22 to write, "We have an esteemed panel of
23 KOLs, national thought leaders, that have
24 agreed to partner with us to deliver this

1 important application-based training.

2 Attached please find more info on the KOL
3 immersion training, curriculum, and a bio
4 fact sheet on each of these KOLs."

5 Do you see that?

6 A. Yes.

7 Q. Okay. And then the next
8 page is -- includes the training agenda.
9 And --

10 A. Sir, may I just clarify?
11 You asked me earlier -- or you stated
12 that I was writing to marketing
13 colleagues.

14 Q. Yeah.

15 A. I want to clarify, this was
16 to -- the e-mail was directed towards the
17 medical affairs and the clinical
18 development team. So these were all MDs
19 and researchers within the Janssen
20 organization.

21 Q. Okay. And to be fair,
22 that's not the extent of it though. You
23 also copied Patricia Yap, Kanitha Burns,
24 and Frank DeMiro, who were all part of

1 your marketing team, right?

2 A. Absolutely, yes.

3 Q. Okay.

4 A. I was just clarifying the
5 "to" line.

6 Q. The "to" line. Fair enough.
7 Fair enough. Thank you for that
8 clarification.

9 And were all of those folks
10 on the "to" line involved in the national
11 sales meeting for the pain force as well?

12 A. My recollection is that some
13 of them could have been involved in only
14 specific areas of the agenda.

15 Q. And when we turn to the
16 agenda, there aren't specific names
17 associated with each time slot except
18 for, at least on this page, the recap on
19 day two between 8:00 a.m. and 8:15 a.m.
20 And that's with Greg Preston and you in
21 the general session before the entire
22 sales force; is that right?

23 A. That's right.

24 Q. And you're recapping all

1 that occurred, yesterday, the day before,
2 Day 1; is that right?

3 A. That's right.

4 Q. Okay. And moving on to the
5 next page, I think this attachment is the
6 KOL information sheet.

7 Do you see that?

8 A. Yes.

9 Q. Okay. Do you know how these
10 physicians got selected to be KOLs at
11 your national sales training for this new
12 pain force?

13 A. I don't recall the exact
14 criteria for how each of these was
15 selected to participate in this meeting.
16 But generally speaking, it would be
17 because they are regarded as being
18 credible and good educators.

19 Q. Are you aware that some of
20 these key opinion leaders, for example
21 Dr. Charles Argoff as just one example,
22 were utilized not just by Janssen, but by
23 multiple different manufacturers as a key
24 opinion leader to convey the message of

1 the undertreatment of pain in America?

2 A. It would not surprise me if
3 any one of these individuals also worked
4 on behalf of other makers of pain
5 medicines.

6 Q. And in fact, as listed in
7 the bio information, the limited
8 information concerning Dr. Charles
9 Argoff, he is a member of the
10 International Association For the Study
11 of Pain, as well as the -- what we have
12 referred to earlier as a pain advocacy
13 group, the American Academy of Pain
14 Medicine and also the American Academy of
15 Neurology; is that correct?

16 MR. GALIN: Objection to
17 form.

18 THE WITNESS: I believe
19 it's -- what's listed here would
20 have represented the most accurate
21 portrayal of his memberships.

22 BY MR. JANUSH:

23 Q. Turning to the next page,
24 you have Dr. Jeffrey Gudin listed as a

1 key opinion leader, one of the nine key
2 opinion leaders at this national sales
3 meeting; is that right?

4 A. That's right.

5 Q. And Dr. Gudin is listed as
6 being a member of the American Medical
7 Society, American Society of
8 Anesthesiology, American Society of
9 Addiction Medicine, American Society of
10 Regional Anesthesia, and the American
11 Pain Society; is that right?

12 A. That is right.

13 Q. Are you aware that the
14 American Medical Society and the American
15 Society of Addiction Medicine, and the
16 American Pain Society are all advocacy
17 groups that received funding and
18 sponsorship from manufacturers like
19 Janssen?

20 MR. GALIN: Objection to
21 form.

22 THE WITNESS: I am not aware
23 if they specifically received
24 funds from any manufacturer or

1 Janssen.

2 BY MR. JANUSH:

3 Q. As you sit here today, you
4 have no knowledge whatsoever as to
5 whether these pain advocacy groups were
6 sponsored by manufacturers such as or
7 including Janssen?

8 MR. ALLEGAERT: Objection to
9 form.

10 THE WITNESS: What I can
11 refer back to is our earlier
12 discussion around corporate
13 sponsorships of advocacy, in that
14 there was some amount of monies in
15 our budget that were earmarked
16 generally for advocacy and handled
17 through our national advocacy
18 director.

19 I can't speak to the precise
20 list you've asked me here, about
21 whether they received any
22 contributions from manufacturers
23 or Janssen.

24 BY MR. JANUSH:

1 Q. Before I move off this
2 exhibit. You stated that you didn't have
3 direct involvement in selecting the key
4 opinion leaders for this national sales
5 meeting; is that right?

6 A. That's right.

7 Q. Did you have any involvement
8 with regard to reviewing the proposed
9 individuals from -- from whomever
10 selected them for participation at this
11 meeting?

12 A. I don't have a direct
13 recollection of a specific review of the
14 individuals prior to extending
15 invitations, no.

16 Q. And who would have been
17 the -- the person at Janssen who extended
18 invitations to these key opinion leaders
19 to present at the national sales meeting
20 for the new pain force?

21 A. I can't speak with any
22 specificity as to who directly extended
23 the invitation. It most likely was
24 either an internal associate or the

1 invitation could have been extended on
2 behalf of Janssen by one of our
3 professional firm agencies that might
4 have handled logistics.

5 Q. Okay.

6 (Document marked for
7 identification as Exhibit
8 Janssen-Lin-17.)

9 BY MR. JANUSH:

10 Q. I'm going to move on to what
11 we are marking as Lin Exhibit 17.

12 This is another e-mail with
13 an attachment. It's JAN-MS-00288407 and
14 JAN-MS-01511433.

15 And I'm going to represent
16 for the record that the attachment
17 doesn't come up within the family of the
18 e-mail. However, through metadata and
19 the title, we pieced together the fact
20 that the attachment is the, based on
21 metadata, has the same date and has the
22 same doc title as what's listed on the
23 third page of the e-mail at Exhibit 17?

24 So I'll hand you Exhibit 17.

1 And this is being provided
2 to you, sir, more so as a confirmation of
3 what we earlier addressed when we went
4 through that Excel spreadsheet and talked
5 about Decile.ten. Do you remember that
6 discussion a bit?

7 A. Yes.

8 Q. And when we talked about
9 Decile.ten, we were addressing the
10 concept that Decile.ten create -- would
11 create slide decks for key opinion
12 leaders. Do you remember that?

13 A. Yes.

14 Q. Okay. So this is an e-mail
15 from Patricia Yap to Carissa Wysocki
16 copying Keith Hofbeck and Amy Bryce dated
17 August 26, 2013, and below Carissa wrote
18 to Tricia -- that's how Patricia, what
19 her -- her -- what she goes by is Tricia;
20 is that right?

21 A. That's right.

22 Q. Okay. And it's addressing
23 the slide decks that Decile.ten was
24 putting together.

1 At the bottom of the e-mail
2 it says, "Per your discussion with Amit,
3 we will put together an HCC slide in the
4 presentation we send you tomorrow for
5 training. Since it is only one slide,
6 does Amit need to be on the call and
7 present? Please advise."

8 And earlier in the string
9 it's addressing, on August 19, 2013, I've
10 highlighted it in orange, "Attached are
11 the final versions of Nucynta ER virtual
12 and Nucynta live, final version of NER
13 live was sent on 8/9. First use dates we
14 are 8/15 for NER live and 8/23 for NER
15 virtual and Nucynta live."

16 Do you see that?

17 A. I do.

18 Q. And then at the bottom of
19 the third page it's addressing the title
20 for the attachment, Nucynta ER virtual
21 version final 8/19/13 and Nucynta live
22 version final 8/16/13. Do you see that?

23 A. I do.

24 Q. And I don't have both of

1 them, I was only able to find one of
2 them.

3 And the reason that they are
4 not associated to the e-mail is because
5 they come -- they were attached earlier
6 in the string and not to the last e-mail
7 in the chain.

8 That said, the document that
9 follows appears to be a slide deck of the
10 type we spoke about when discussing the
11 budget.

12 Is this something that looks
13 like what Decile.ten might have produced
14 for key opinion leaders to utilize when
15 discussing Nucynta?

16 A. Yes, this looks like the
17 work product that would have been used
18 for promotional education activity,
19 delivered probably in a speaker bureau.

20 Q. Okay. Does the name
21 Dr. Gharibo ring a bell?

22 A. No, sir.

23 (Document marked for
24 identification as Exhibit

1 Janssen-Lin-18.)

2 BY MR. JANUSH:

3 Q. I'm going to hand you what

4 I've marked as Lin Exhibit 18.

5 JAN-MS-01079820. And it's an e-mail from

6 Frank DeMiro to others, including you,

7 Patricia Yap, Dominic Lazzaro, Roxanne

8 McGregor-Beck and others, and it's

9 addressing Tim and Vandana. Who are

10 Tim -- Timothy Conniff and Vandana

11 Kataria?

12 A. My recollection is that

13 Vandana was a district manager in the

14 sales force, the PriCara sales force.

15 And Tim Conniff was a region business

16 director in the sales force, most likely

17 the direct supervisor of Vandana.

18 Q. Okay. And this is

19 addressing that, quote, Frank DeMiro

20 wrote, "I have spent a good deal of time

21 this week understanding what transpired

22 at Dr. Gharibo's speaker program last

23 week, and the implications that it could

24 have on our business.

1 "After careful review and
2 much discussion with all of you, I just
3 got off the phone with Dr. Gharibo, and
4 informed him that he will be removed from
5 our speaker bureau. Without going into
6 all of the details, I gave him a high
7 level overview of the key areas of
8 concern. While he was certainly
9 disappointed, he expressed sincere
10 appreciation for the call and also for
11 the strong partnership we as an
12 organization have had with him over the
13 last three years."

14 Having read this quote and
15 addressed this e-mail in part with you,
16 does it refresh your recollection at all
17 in terms of who Dr. Gharibo was or what
18 happened in this time period?

19 A. No, sir. No direct
20 recollection of Dr. Gharibo.

21 Q. Okay. I'm going to
22 represent to you that -- that Dr.
23 Christopher Gharibo works as a pain
24 specialist at NYU Langone Health.

1 So as you sit here today,
2 you don't recall whether Dr. Gharibo
3 expressed that opioids should not be used
4 as a first line treatment when he was
5 speaking about opioid products; is that
6 right, you don't recall that?

7 A. Is there a specific --

8 MR. GALIN: Objection to
9 form.

10 THE WITNESS: Is there a
11 specific publication or something
12 that we are talking about?
13 Because all I'm looking at here is
14 an e-mail about --

15 BY MR. JANUSH:

16 Q. I'm just asking you a
17 question --

18 A. -- summarizing a telephone
19 conversation.

20 Q. Just asking you a question.

21 A. Could you repeat the
22 question?

23 Q. Sure. As you sit here
24 today, you don't recall whether

1 Dr. Gharibo expressed that opioids should
2 not be used as a first-line treatment
3 when he was speaking about opioid
4 products?

5 A. No.

6 Q. Okay. Do you recall hearing
7 that Dr. Gharibo was concerned that
8 opioids were being overutilized and other
9 treatment modalities existed that should
10 be tried first?

11 A. No.

12 Q. Do you recall hearing that
13 Dr. Gharibo felt that doctors were
14 dropping the ball by overprescribing
15 opioids too much?

16 MR. GALIN: Objection to
17 form.

18 THE WITNESS: No.

19 BY MR. JANUSH:

20 Q. But what you can see from
21 this e-mail is that Dr. Gharibo got
22 removed from Janssen's speaker bureau,
23 without getting into all of the details,
24 quote.

1 Do you see that?

2 A. I do see that. That's what
3 is written here.

4 Q. And you can also see that
5 what's written here is that the
6 implications of Dr. Gharibo speaker
7 program last week could have a negative
8 impact on Janssen's business.

9 Do you see that as well,
10 right?

11 A. I don't see the word
12 "negative impact", sir.

13 Q. Correct. But that is the
14 intent that's being conveyed in this
15 e-mail, isn't it?

16 A. I can't speak to the intent
17 that was conveyed in the e-mail that was
18 written by Frank.

19 Q. So let's -- let's go through
20 it.

21 "I have spent a good deal of
22 time this week understanding what
23 transpired at Dr. Gharibo's speaker
24 program last week and the implications

1 that it could have on our business.
2 After careful review and much discussion
3 with all of you, I just got off the phone
4 with Dr. Gharibo and informed him that he
5 will removed from our speaker bureau."

6 Sir, you don't remove people
7 from a speaker bureau when their
8 statements could have a positive impact
9 on your business, right?

10 MR. GALIN: Objection to
11 form.

12 THE WITNESS: You typically
13 remove a speaker from the speaker
14 bureau because they're found to
15 not necessarily be in the spirit
16 of a promotional message.

17 BY MR. JANUSH:

18 Q. Okay. Moving on.

19 Do you remember earlier in
20 the deposition we were discussing the
21 concept that Nucynta's website links to
22 Prescribe Responsibly and -- or I was
23 discussing and you weren't sure whether
24 there was a linking between the websites?

1 A. Yes, I recall that
2 conversation.

3 (Document marked for
4 identification as Exhibit
5 Janssen-Lin-19.)

6 BY MR. JANUSH:

7 Q. I'm going to hand you an
8 exhibit that is Bates-numbered
9 JAN-MS-0076628. It's Lin-19.

10 MR. JANUSH: And I'm going
11 to ask counsel to disregard --
12 since the actual exhibit doesn't
13 have this sticker on it, that it's
14 a copy from the prior deposition.
15 Disregard the sticker. I've
16 covered it over with the Lin
17 exhibit sticker.

18 BY MR. JANUSH:

19 Q. So moving to the last page
20 of the exhibit, in very small font, is a
21 diagram of how linking works on the web.
22 And I'm going to try and zoom in here.

23 And it says, "This picture
24 gives a good description of how linking

1 works. As each relevant site links to
2 another, they form a trust relationship
3 between them for that particular term or
4 subject, usually qualified by the anchor
5 text. Then as all of them begin linking
6 to one another, a larger cloud of
7 relevance is formed, creating a larger
8 environment of trust among all of the
9 sites which search engines use to
10 determine how a site should rank in
11 search engine results."

12 Do you see that?

13 A. I do see that.

14 Q. Do you understand as a
15 marketing director or as someone who has
16 been involved in marketing, certainly
17 during the age of the internet, this
18 concept of linking between sites and
19 creating a more trusted relationship on
20 the web as one site links to another and
21 a search engine accords those sites with
22 a greater ranking in search results?

23 A. I have to say I'm not very
24 educated or knowledgeable about the

1 topic.

2 Q. Okay. So you don't have --
3 fair to say that you don't have much
4 experience with regard to web-based
5 marketing?

6 MR. GALIN: Objection to
7 form.

8 THE WITNESS: I think it
9 depends on -- I am familiar with
10 the notion that the internet is
11 used as a vehicle for lots of
12 marketing -- marketing types of
13 services and products.

14 BY MR. JANUSH:

15 Q. Have you -- have you heard
16 of the concept of search engine
17 optimization?

18 A. I have heard the term
19 "search engine optimization."

20 Q. And in conjunction with
21 that, have you heard about having
22 multiple sites that link to each other to
23 create a greater zone of trust amongst
24 those sites?

1 A. That concept is not one that
2 I'm familiar with.

3 Q. Okay. Well, this was --
4 this was produced by Janssen to explain
5 the document or the pages that precede it
6 concerning Prescribe Responsibly and
7 Nucynta ER.

8 And so do you see over here
9 in the upper left-hand corner, "Nucynta
10 resources, managing chronic pain," and
11 that links to PrescribeResponsibly.com
12 pain assessment resources?

13 A. I do.

14 MR. GALIN: Objection to
15 form.

16 BY MR. JANUSH:

17 Q. Do you see that?

18 A. I see -- I see what you're
19 circling. It's the first line of this
20 table.

21 Q. Okay. And in fact, there's
22 another -- one, two, three, four, five,
23 six, seven, eight, nine, ten -- 11
24 different -- well, they're not all

1 different. So let me -- let me break
2 that down.

3 There is -- in the second
4 line, a different page within the
5 Nucynta.com site that's about acute pain
6 management. And that's a linking to
7 assessment resources as well.

8 Do you see that?

9 A. Yes, I see that.

10 Q. And then there's a third
11 Nucynta page addressing professional
12 resources and that's linking to Prescribe
13 Responsibly page assessment resources.

14 Do you see that?

15 A. I do.

16 Q. And then there's another
17 Nucynta page at healthcare professional
18 resources, and that's linking to
19 PrescribeResponsibly.com hospital
20 resources.

21 Do you see that?

22 A. I see that.

23 Q. And then there's another
24 Nucynta page concerning dosing and

1 administration dosing guide. And that's
2 linking to pain assessment resources at
3 Prescribe Responsibly.

4 Do you see that?

5 A. Yes.

6 Q. And then there's another
7 Nucynta page concerning opioid withdrawal
8 study. And that's linking to risk
9 assessment resources page at
10 PrescribeResponsibly.com.

11 Do you see that?

12 A. Yes.

13 Q. And then there's Nucynta
14 page for safety profiles, opioid
15 withdrawal -- forgive me -- that's what
16 I've addressed just before, that that's
17 linking to risk assessment resources.

18 And then there's healthcare
19 professional resources on the Nucynta
20 page. And that's linking to pain
21 assessment resources, but I believe
22 that's redundant of one of the ones that
23 I've addressed above.

24 So I'll stop there and just

1 say, fair to say that there were a few
2 different subpages on Nucynta.com that
3 are shown in this document to be linking
4 to Prescribe Responsibly resources, true?

5 A. According to the document,
6 which I have not seen before, and based
7 on the column headings, I would have to
8 assume it's representing that there is a
9 link from one site to another.

10 Q. And if you go to that last
11 page, this is addressing the purposeful
12 nature of linking, isn't it?

13 MR. GALIN: Objection to
14 form.

15 BY MR. JANUSH:

16 Q. The statement that, "This
17 picture gives a good description of how
18 linking works. As each relevant site
19 links to another, they form a trust
20 relationship." And I could read on, but
21 I'm going to end it there.

22 A. I can't speak to the
23 validity or the use of this. I
24 acknowledge that the words are on this

1 page, on this exhibit. I don't know how
2 this was used, so I don't have much more
3 to add to the validity of what it says.

4 Q. This next exhibit may go
5 pretty quickly. It's Lin Exhibit 20.

6 (Document marked for
7 identification as Exhibit
8 Janssen-Lin-20.)

9 BY MR. JANUSH:

10 Q. It's an e-mail,
11 JAN-MS-02097372, and it's dated
12 January 12, 2014. It's sent by Dan
13 Cohen, senior vice president government
14 relations and public policy. You are
15 copied on the e-mail. And it's
16 addressing the ADF coalition organization
17 conference call for Tuesday, January 21,
18 2014. And you are copied on the
19 attachment.

20 Well, before I get to the
21 attachment, at the bottom of the e-mail
22 it says, "Dear all, please find attached
23 a list of the organizations that have
24 indicated a desire to join or consider

1 joining the initial formation of the ADF
2 coalition. Please review the list. Let
3 me know if your organization is in the
4 correct area and if you will be able to
5 join the conference call."

6 And then above that is Ron
7 Kuntz writing back, "All, let's make sure
8 we have appropriate people are on this
9 call taking place on January 21st so we
10 know what activities this coalition is
11 working on and to ensure we have a
12 voice."

13 Do you see that?

14 A. I do.

15 Q. Then when we turn to the
16 agenda, it's addressing some of the
17 invited participants. I see Grunenthal
18 USA, the Center For Lawful Access and
19 Abuse Deterrence. I'm not going to name
20 them all, but I'm going to focus on some.
21 RADARS, and certain co-defendants of
22 Janssen, in this case Teva
23 Pharmaceuticals, Purdue Pharma, Endo
24 Pharmaceuticals, Mallinckrodt

1 Pharmaceuticals.

2 And my question for you is,
3 do you know whether Janssen joined this
4 abuse deterrence formulations coalition?

5 A. I do not know.

6 Q. Okay. Who would be the --
7 the best person to talk to ask that
8 question?

9 Would it be Ron Kuntz that
10 suggested having a voice on that call?

11 A. I don't know if he's the
12 best person, but he is --

13 Q. A person.

14 A. He is a person.

15 (Document marked for
16 identification as Exhibit
17 Janssen-Lin-21.)

18 BY MR. JANUSH:

19 Q. Moving on to Exhibit 21.
20 JAN-MS-00984287. This is, as I
21 understand it, an agreement you entered
22 into concerning a sponsorship proposal
23 from the Community Anti-Drug Coalitions
24 of America to provide funding of \$120,000

1 to sponsor the Smart Moves Smart Choices
2 program in December of 2013. Do you
3 remember entering into this agreement?

4 A. No, I don't.

5 Q. Going to the third page, is
6 that your signature?

7 A. That is not my signature.

8 Q. Is that your electronic
9 signature that would have been used on a
10 PDF?

11 A. It has -- it has to be
12 something electronic. It's not my
13 personal signature.

14 Q. Okay. As you sit here
15 today, are you -- are you -- I understand
16 that you don't recall entering into this,
17 but are you taking the position that you
18 didn't enter into this or that you just
19 don't recall -- you don't recall having
20 electronically signed this?

21 A. I'm taking the position that
22 I don't recall reviewing this document
23 and signing it.

24 Q. Okay. You do know however

1 that in 2000 and -- that at some point in
2 time in 2013, 2014, that Janssen did
3 partner with Smart Moves Smart Choices,
4 right?

5 MR. GALIN: Objection.

6 BY MR. JANUSH:

7 Q. We discussed that earlier
8 within the budget discussion?

9 MR. GALIN: Objection to
10 form.

11 THE WITNESS: I -- yes, I do
12 recall in the context of that
13 budget discussion there was a
14 support for Smart Moves Smart
15 Choices.

16 BY MR. JANUSH:

17 Q. And we talked about the
18 toolkit that Smart Moves Smart Choices
19 would have provided Janssen with, do you
20 remember that?

21 A. We -- I recall our
22 discussion was that there was a line item
23 that mentioned something about a
24 toolkit.

1 (Document marked for
2 identification as Exhibit
3 Janssen-Lin-22.)

4 BY MR. JANUSH:

5 Q. Moving on to Lin Exhibit 22.

6 This is a --

7 MR. JANUSH: Bless you.

8 BY MR. JANUSH:

9 Q. This is a parent e-mail with
10 an attachment. Parent e-mail is
11 JAN-MS-00362016, attachment
12 JAN-MS-00362018.

13 It's an e-mail from you.

14 And this is addressing quality care
15 coalition for patients in pain.

16 And an attachment titled
17 Patients in Pain: How U.S. Drug
18 Enforcement Administration Rules Harm
19 Patients in Nursing Facilities. A survey
20 of clinicians.

21 Do you see that?

22 A. Yes.

23 Q. Okay. And you were
24 forwarding this on to Lisa Ferguson

1 stating, "Lisa, since your team has much
2 experience with LTC, please see attached.
3 Sorry for large file."

4 Was LTC referring to
5 long-term care?

6 A. Yes, LTC stands for
7 long-term care.

8 Q. Okay. What was your intent
9 in forwarding on this article to Lisa
10 Ferguson?

11 A. Just sharing information.

12 Q. Can you elaborate?

13 A. Well, as I'm looking at this
14 e-mail, there's someone from an outside
15 organization writing to Robyn, Robyn
16 forwards to a number of folks across a
17 variety of functional areas.

18 At the time here, in 2010 --
19 2010 if my recollection is correct, Lisa
20 was one of the national sales directors
21 in the PriCara sales force. So I did as
22 folks often do, which is pass things
23 along as information.

24 Q. So let's go to the second

1 e-mail of the string, because I think
2 there's a little more to it. It states,
3 "FYI, spoke with ASCP today. Reviewing
4 these documents and wanted to pass on per
5 interests in pain and elderly
6 populations, legislation around
7 E-prescribing, C-IIs in skilled nursing
8 facilities, et cetera. Been invited to
9 participate in the Quality Care Coalition
10 For Patients in Pain. We would be the
11 only Pharma rep."

12 I'll stop there. The "we"
13 that's being referred to as the only
14 Pharma rep is Janssen, correct?

15 MR. GALIN: Objection to
16 form.

17 THE WITNESS: I -- I
18 can't -- I can't speak as to
19 whether Robyn meant that. But I
20 would have to -- based on what's
21 written here, I think it's a
22 likelihood she's referring to "we"
23 as an entity.

24 BY MR. JANUSH:

1 Q. Right. And Robyn's a
2 Johnson & Johnson employee, right?

3 A. Yes. Robyn Kohn is a J&J
4 employee.

5 Q. Okay. And she's addressing,
6 "We will address alignment strategies
7 before moving forward. Robyn."

8 And then you forward it to
9 Lisa, and address, "Since your team has
10 much experience with LTC, please see
11 attached."

12 Do you know if after
13 forwarding this on, Janssen aligned
14 itself with the Quality Care Coalition
15 For Patients in Pain?

16 A. No, I don't recall what
17 transpired -- what transpired from this
18 e-mail.

19 (Document marked for
20 identification as Exhibit
21 Janssen-Lin-23.)

22 BY MR. JANUSH:

23 Q. I'm going to hand you what's
24 been marked Lin Exhibit 23. It's

1 Bates-numbered JAN-MS-02525303.

2 This appears to be a meeting
3 invitation e-mail sent to you and others
4 on the Nucynta team about a meeting for
5 recommended revisions to the label of
6 Nucynta ER.

7 It starts with, "Dear all, I
8 am scheduling this meeting to discuss the
9 LC-recommended revisions in the U.S.
10 package insert to align the company
11 position with Duragesic. I identified
12 three main points to focus on."

13 Before we get into those
14 three main points, LC-recommended
15 revisions, does that stand for label
16 change recommended revisions?

17 A. Forgive me. I just need a
18 moment to review the context here.

19 My recollection is only
20 around the acronym. In the subject line
21 you asked me what post-LC means. I don't
22 know what post-LC means. LWG my
23 recollection is that that stands for
24 label working group.

1 Q. And it looks like Teodora
2 Doherty is suggesting three main points
3 to focus on.

4 Do you see that?

5 A. Yes.

6 Q. And one of the three main
7 points to focus on is addressed in --
8 under the "Nucynta ER is" section.

9 And I'm going to go down to
10 the third bullet.

11 "Nucynta ER is a long-acting
12 extended-release opioid pain medicine
13 that can put you at risk for overdose and
14 death. Even if you take your dose
15 correctly as prescribed, you are at risk
16 for opioid addiction, abuse and misuse
17 that can lead to death."

18 Do you see that?

19 A. I do.

20 Q. That language that was being
21 proposed to this group was not adopted,
22 was it?

23 A. Sir, I don't know whether
24 that was adopted. I only see that that

1 was a point of discussion that was raised
2 for this teleconference.

3 Q. So a point of discussion
4 raised for the teleconference was whether
5 Janssen should increase the warning about
6 the risk of death when using Nucynta,
7 true?

8 MR. GALIN: Objection to
9 form.

10 THE WITNESS: No. I think
11 it's important to look at the
12 context of this e-mail, is that
13 the author, Teodora, raised a
14 couple of points for discussion
15 based on, as I read the first
16 line, in consideration for
17 aligning with Duragesic.

18 BY MR. JANUSH:

19 Q. Right. I'm with you. And
20 so in consideration of aligning the USPI,
21 the U.S. package insert, with the
22 company's position concerning Duragesic,
23 a discussion was raised as to whether the
24 Nucynta warning concerning the risk for

1 overdose and death should be revised,
2 true?

3 MR. GALIN: Objection to
4 form.

5 THE WITNESS: All I can
6 speak to is it appears from this
7 e-mail that Teodora Doherty is
8 suggesting that these are the
9 points that would be relevant for
10 the discussion. I don't know if
11 anything else came up. And I
12 don't know that all of these were
13 discussed. I just know that it's
14 represented in the e-mail.

15 BY MR. JANUSH:

16 Q. And the best way to
17 determine whether Janssen adopted the
18 position, the discussion point as to
19 whether the warning should be modified to
20 include this language would be to look at
21 the next ensuing package insert, fair?

22 MR. GALIN: Objection to
23 form.

24 THE WITNESS: I don't think

1 that's fair.

2 BY MR. JANUSH:

3 Q. Why not?

4 A. I think in label
5 negotiations, there are things that
6 sponsors may discuss, but ultimately
7 anything that ends up in the package
8 insert is through alignment with the FDA.

9 Q. Right. The FDA does not
10 prevent a manufacturer from ever
11 increasing its warning language, does it?

12 MR. GALIN: Objection to
13 form.

14 THE WITNESS: I don't know.
15 I'm not an authority on how the
16 FDA operates. I'm only speaking
17 to the fact that these are points
18 that are raised in an e-mail.

19 BY MR. JANUSH:

20 Q. And so I'm saying -- making
21 the point that one would know whether
22 this language was adopted by looking at
23 the label. And your position is, not
24 necessarily, because the FDA might not

1 have permitted an increased warning; is
2 that right?

3 A. I think that is one point to
4 consider. The other point is this was
5 what appears to be aligning -- aligning a
6 company position with another product in
7 the portfolio. So there are more than
8 one variable here.

9 Q. But that actually has
10 nothing to do with the question that I'm
11 addressing. I'm addressing whether a
12 company can raise -- increase the degree
13 and nature of its warning in its package
14 insert. And you're saying that the next
15 ensuing label may not be indicative of
16 whether the company sought to increase
17 its warning because the FDA potentially
18 could put a halt to a company creating a
19 stronger warning that is more pro -- more
20 protective of patients?

21 MR. GALIN: Objection to
22 form.

23 THE WITNESS: I think those
24 are your words, not mine.

1 BY MR. JANUSH:

2 Q. But that's the upshot, isn't
3 it?

4 MR. GALIN: Objection to
5 form.

6 THE WITNESS: I think that's
7 unfair to represent what I'm
8 saying.

9 I am literally saying that
10 these are words contained in an
11 e-mail which looks to be within
12 the context of a meeting invite.
13 I don't know. I can't speak to
14 how the discussion resulted and I
15 can't speak to what did or didn't
16 ensue from that discussion.

17 (Document marked for
18 identification as Exhibit
19 Janssen-Lin-24.)

20 BY MR. JANUSH:

21 Q. I've marked Lin Exhibit 24,
22 as JAN-MS-0087195. This is an e-mail
23 from you to Frank DeMiro, amongst others,
24 including Ron Kuntz. And you're sharing

1 another e-mail that followed below that
2 from you to Kim Park and Bruce Moskovitz
3 where you addressed a draft from Bruce
4 Moskovitz and added a commercial
5 marketing perspective in maroon text that
6 didn't copy in maroon here, but I'm going
7 to have you turn to Page 2 of this
8 e-mail. And I'm going to bracket on the
9 Elmo what appears in maroon text as your
10 added paragraphs. It's the last two
11 paragraphs in the e-mail.

12 And, "This concerned a study
13 published Monday in the Annals of
14 Internal Medicine, that found that more
15 doctors are prescribing oxycodone,
16 morphine, and other opioid painkillers
17 for back pain, arthritis, and headache,
18 leading to potentially fatal overdoses."

19 Do you remember weighing in
20 on this topic while employed at Janssen?

21 A. I don't -- I don't recall
22 writing or addressing this particular
23 article. I was 19 days into my
24 assignment. And -- but it would be

1 customary to review, if I was asked for
2 an opinion.

3 Q. While you were employed at
4 Janssen, were you ever part of the CDT,
5 the compound development team?

6 A. The compound development
7 team, I was -- I think the term was I was
8 a standing guest because the compound
9 development team usually comprises
10 someone from the global marketing team.
11 But as the U.S. representative, I was
12 often a guest.

13 Q. Okay. Were you ever part of
14 the core task team, the CTT?

15 A. I'm not familiar with the
16 term "CTT."

17 Q. Were you ever involved with
18 drafting a or reviewing the REMS for
19 tapentadol?

20 A. I do not recall drafting or
21 reviewing a REMS document.

22 Q. Never reviewed the REMS
23 whatsoever?

24 A. I think in -- it would be my

1 recollection that I probably have seen a
2 finished version of a REMS that was
3 handed to offices.

4 (Document marked for
5 identification as Exhibit
6 Janssen-Lin-25.)

7 BY MR. JANUSH:

8 Q. I've marked as Exhibit 25,
9 Lin Exhibit 25, JAN-MS-01057540. This is
10 the tapentadol REMS.

11 Do you recall seeing this
12 risk evaluation mitigation strategy or
13 risk management strategy for tapentadol?

14 A. I believe I've seen things
15 like this, but I can't specify if this is
16 the exact version I have ever seen.

17 Q. What's the goal of a REMS?

18 A. Well, consistent with --
19 REMS is basically an evaluation of the
20 risks associated with the use of a
21 particular product, to my understanding.

22 And then there's a
23 significant amount of investment or
24 resources that are put against it to

1 mitigate that risk. So it's evaluation
2 and mitigation of identified risks
3 associated with the use of a product.

4 Q. You played no role
5 whatsoever in drafting or reviewing a
6 REMS during any of your time involved in
7 overseeing sales and marketing of Nucynta
8 IR or ER?

9 A. I have no recollection of
10 crafting or specifically reviewing a REMS
11 document.

12 Q. Okay.

13 MR. JANUSH: At this point
14 I'm going to stop and turn the
15 floor over.

16 MR. GALIN: Can I ask for
17 just a five-minute break?

18 MR. JANUSH: Of course.

19 MR. GALIN: To streamline
20 for anything that I might have to
21 ask the witness.

22 THE VIDEOGRAPHER: The time
23 is 6:09 p.m. Going off the
24 record.

1 (Short break.)

2 THE VIDEOGRAPHER: The time
3 is 6:17 p.m. Back on the record.

4 MR. JANUSH: This is Evan
5 Janush for plaintiffs. I'm just
6 performing a housekeeping matter
7 and marking Lin Exhibit 26 as the
8 demonstrative, the notes that I
9 created while Mr. Lin was
10 testifying. And that's all I
11 have.

12 (Document marked for
13 identification as Exhibit
14 Janssen-Lin-26.)

15 MR. GALIN: Great.

16 - - -

17 EXAMINATION

18 - - -

19 BY MR. GALIN:

20 Q. This is Ross Galin for the
21 Johnson & Johnson Janssen defendants.
22 Mr. Lin, I don't want to take too much
23 time. But I do want to have an
24 opportunity to ask you a couple of

1 questions.

2 Starting with, you were
3 involved, were you not, in the
4 development of marketing materials?

5 A. I think it's fair to say
6 that as a brand leader, I oversaw a team
7 that directly developed the marketing
8 materials.

9 Q. All right. Can you tell me
10 first what is the purpose of putting
11 together marketing materials?

12 A. Marketing materials, at a
13 high level, are basically a means to
14 effectively communicate the product
15 profile in a way that is compelling,
16 represents the data contained in the PI,
17 so that engagement with customers can be
18 productive and educational.

19 Q. Okay. You mentioned the PI.
20 What role does the PI, if any, play in
21 the marketing materials?

22 A. The PI serves as a home base
23 from which the items like the clinical
24 trials would be derived or pulled. A lot

1 of the data is pulled from a PI.

2 In addition, when a
3 representative engages with an office,
4 they always leave a PI immediately before
5 or after their discussion with the
6 physician.

7 Q. Does information have to
8 come solely from the PI to be included in
9 any marketing claims or materials?

10 A. I would say the majority of
11 what's on the marketing materials does
12 come from a PI. But there are instances
13 where there are other data sources. It
14 could be publications or other studies.
15 So long as that data is not inconsistent
16 with what's in the label, then it can be
17 a judgment as to whether it's included in
18 the marketing materials.

19 Q. Are there any obligations to
20 present data on safety in your marketing
21 materials?

22 A. Yes. In the message, the
23 dialoguing or the presentation of the
24 educational materials that are by a sales

1 representative, in the -- in the case of
2 visual aids, whether they be paper or
3 electronic, it's always first and
4 foremost to show the important safety
5 information upfront. And that has to be
6 covered before moving into the other core
7 messages contained in the visual aid.

8 Q. Okay. Can you walk me
9 through, if you would, the process of
10 creating marketing materials?

11 A. So I'll use, as an example,
12 the most common marketing materials is in
13 the form of a visual aid, which is used
14 by a sales representative to educate a
15 physician customer or a nurse.

16 The visual aid is developed,
17 usually in partnership with a third-party
18 advertising agency. The concepts and the
19 copy, which would include all the facts
20 and figures, are submitted together. And
21 they are reviewed by something called a
22 promotional review committee. Sometimes
23 they take different names in different
24 firms. That committee is comprised of

1 functional experts, in medical,
2 regulatory, legal, healthcare compliance.
3 That would be the core team. And they
4 would review the piece for accuracy, and
5 with the lens of their functional
6 expertise to ensure that, again, it's
7 accurate, and the intent of the piece is
8 substantiated with the data that's cited.

9 Q. Can a piece be used by the
10 company or its sales representatives
11 without going through the promotional
12 review committee process?

13 A. No. Any piece that's used
14 by a sales representative or other
15 customer-facing team members need to
16 be -- they need to use materials that are
17 reviewed by a promotional review
18 committee.

19 Q. And are sales
20 representatives required to use visual
21 aids or detail pieces, so to speak, in
22 any interaction with HCPs?

23 A. The intent of an interaction
24 with an HCP is to educate. And the

1 visual aid is -- visual aid or a clinical
2 piece would be the preferred way to
3 educate a doctor on clinical material --
4 clinical content.

5 It is highly desirable so
6 that you can cite the information
7 accurately. And usually it helps to have
8 something to supplement the points.

9 Q. You testified earlier today
10 when Mr. Janush was asking you a couple
11 of questions about relying on others to
12 ensure that the claims were accurate
13 and/or that marketing pieces had what was
14 necessary. Was it the PRC process that
15 you were referring to or some other
16 process, or people?

17 A. I was referring -- in that
18 discussion, I was referring to the PRC
19 process where materials were reviewed by
20 this cross-functional team to ensure
21 accuracy.

22 Q. We've been talking about
23 materials. Is it simply the materials
24 that go through PRC, or do other things

1 go -- such as claims generally go through
2 PRC?

3 A. Any content that is shared
4 with a customer outside the four walls of
5 the building would be going through PRC,
6 inclusive of visual aids, speaker
7 programs, websites.

8 Q. Not to belabor the point
9 because it's long in the day, but just to
10 be clear, you said that the PRC has
11 regulatory, medical, healthcare
12 compliance and legal?

13 A. Those are central members of
14 the PRC, yes.

15 Q. Okay. And what roles do
16 each of them play in the PRC?

17 A. In reviewing a piece, each
18 of those individuals reviews, first and
19 foremost, with their functional expert
20 hat on. But also in weighing the
21 totality of the piece, it's important for
22 them to collaborate as a team to make
23 a -- to make a judgment as to if all the
24 information fits together in a way that

1 is consistent with the spirit of the
2 indication in the label.

3 Q. We spoke earlier today about
4 some sales rep training. Do you recall
5 that?

6 A. Yes.

7 Q. And do you recall Mr. Janush
8 showed you some written portions or
9 printouts of video training?

10 A. Yes, I do.

11 Q. Can you explain to me how
12 those types of training fit into the
13 overall training that sales reps receive
14 both in general and nonspecific pieces?

15 A. In general, based on my time
16 working on the Nucynta brand, training
17 programs for a sales rep can comprise
18 those types of video scripts that we
19 viewed earlier. Those may be utilize to
20 do provide an overview of the training
21 program. But a training program would
22 also entail other elements, which we did
23 not review today, such as modules on
24 clinical data, on safety specifically.

1 And the training program
2 would also culminate in practice using a
3 visual aid or key resources, also some
4 sort of exam, whether it be written or a
5 role play with a sales trainer.

6 Q. You mentioned the visual
7 aids and you mentioned when we were
8 speaking about those training pieces
9 before, that they were meant to be used
10 with flash cards and visual aids.

11 Do you recall that?

12 A. Yes, I do.

13 Q. How, if at all, do you think
14 the visual aids would have affected or
15 related to what was in the training that
16 we looked at?

17 A. I think in the scripts we
18 reviewed earlier that I think pertained
19 to some training videos, they made
20 reference to visual aids. So in -- in
21 the actual training for the use of the
22 visual aid, there would be additional
23 content or classes, online classes or
24 modules, or in-person classes that would

1 go through in much more detail about the
2 points highlighted in the visual aid
3 regarding clinical efficacy, and would
4 put a much finer point on the specific
5 claims or representations of the product
6 in the visual aid or any other flash
7 card.

8 Q. Would you expect -- would
9 the -- is it possible for the language in
10 the visual aids to deviate or expand on
11 the information in the training modules?

12 A. It is possible that the
13 wording in the visual aid is different
14 than what is provided in a training video
15 that may be more of an introductory video
16 to the overall training program.

17 The language in the visual
18 aid is usually -- contains things around
19 the product efficacy, product
20 tolerability, safety information.

21 And so the exact wording of
22 what's contained in the visual aid may
23 not always appear, for example, in a
24 script which is designed to introduce an

1 overall curriculum.

2 Q. Shift gears, hopefully to my
3 last subject, to sales comp and
4 incentives. We looked earlier today at a
5 sales comp for -- I think it was 2010
6 Nucynta, slide deck that had some
7 baseline and targets and explained the
8 plan to the sales force. Do you recall
9 that?

10 A. Yes.

11 Q. I can pull that out if folks
12 need to look at it.

13 MR. GALIN: Do you need to
14 look at it?

15 BY MR. GALIN:

16 Q. Let me ask you a couple of
17 questions. One of the things -- well
18 actually, withdrawn. Let me start with
19 this.

20 Can you give me a basic
21 understanding of the breakdown of a
22 representative's income or compensation
23 between base salary and comp?

24 A. The majority -- in the --

1 typically in the pharmaceutical industry,
2 the overall percentage of compensation
3 for a sales rep is primarily comprised of
4 their base salary.

5 Incentive comp is exactly
6 that, it's above -- over -- it's over
7 base compensation based on performance.

8 But the majority, for most
9 sales reps, the majority of their income
10 will be represented by the base salary.

11 Q. And is that true of the
12 Nucynta sales teams that you were
13 involved with at your time at Janssen?

14 A. Yeah, my recollection of the
15 overall incentive structure or the
16 incentive scheme was that the base salary
17 represented the majority of their overall
18 compensation.

19 Q. Okay. When Mr. Janush was
20 asking you about the model that was
21 presented and had an example, you had
22 suggested that it's not exactly
23 representative of what sales reps
24 normally would achieve or earn. Can you

1 expound on that, or explain what you
2 meant by that?

3 A. Yes. I think the -- the
4 example that was provided in that
5 particular incentive compensation
6 overview, I would characterize, based on
7 experience, as being on the higher end of
8 a potential payout. And that did not
9 apply to the vast majority of the folks
10 in the sales organization. It was -- I
11 think the spirit of those documents is to
12 motivate a sales rep to perform at their
13 best.

14 Q. Why do you have to include
15 incentive comp?

16 A. My understanding of
17 incentive comp is that -- for -- for two
18 reasons. Number one, sales forces
19 work -- they are field based. They work
20 alone. And they typically are very
21 competitive and incentive comp is there
22 to drive their overall competitiveness.
23 But I think when you're working alone
24 in -- in a non-office setting, mostly

1 living out of your car, incentive comp
2 serves to provide some sort of
3 incentive -- some sort of reward for the
4 efforts that are taken day-to-day.

5 Q. And are there guardrails or
6 procedures in place to mitigate against
7 that incentive leading to improper
8 conduct by the reps?

9 MR. JANUSH: Objection.

10 THE WITNESS: The incentive
11 plan is set forth in the beginning
12 of the year. And as you saw from
13 that example, there are guidelines
14 for qualifying, there are
15 guidelines for which customers can
16 apply to an incentive program.

17 And so there are, in my
18 recollection -- the plans are
19 structured to provide guidance
20 around what constitutes good
21 performance.

22 And so at the end of every
23 quarter, when the incentives are
24 being calculated, it is -- it is

1 the responsibility of the sales
2 leadership, along with healthcare
3 compliance and human resources, to
4 ensure that the results that are
5 being used to calculate incentive
6 comp have been derived based on
7 proper performance.

8 BY MR. GALIN:

9 Q. Are sales reps monitored or
10 reviewed in any way to ensure compliance?

11 MR. JANUSH: Objection.

12 THE WITNESS: From the
13 standpoint of -- of performance
14 management, it is very -- it's
15 commonplace for district managers
16 to ride with their sales reps to
17 ensure they are able to coach
18 them, to ensure that they are
19 communicating and educating
20 customers optimally. So coaching
21 is a -- is a key component of it.

22 In addition, healthcare
23 compliance officers also do ride
24 with reps. And so while those are

1 representative samplings, there is
2 a -- there are checks to ensure
3 that reps are performing at their
4 best and according to their job
5 description and in line with the
6 product label.

7 BY MR. GALIN:

8 Q. I hope to be my final
9 question:

10 Can you share with us the
11 role that contests play in sales comp?

12 A. On select instances, a sales
13 leadership team may decide to fund and
14 execute a contest. The contests are --
15 the structure can be different depending
16 on the incentive plan.

17 Typically they are just a
18 little bit of a booster, usually to
19 encourage teamwork at a district level,
20 or at a level higher than the individual.
21 And they're -- they're very common just
22 to pull a team together to either get off
23 to a really good start in the year, or to
24 have a strong close.

1 And so while the incentive
2 plan rewards the individual performance
3 of a sales rep, many times a contest will
4 be used to bring a district together and
5 say, if we can all hit this goal, we may
6 be eligible for a little bit extra in
7 terms of reward.

8 I do think it's important to
9 note that the contests are in no way
10 overshadow the incentive comp. They are
11 a much smaller amount.

12 My recollection is contests
13 would have payouts between 500 and
14 \$1,000. So not as significant as the
15 overall potential payout of an incentive
16 plan.

17 MR. GALIN: Contrary to the
18 words of the federal judge for
19 whom I clerked, he said never
20 trust a lawyer who says he only
21 has one more question. I'm going
22 to stop there.

23 - - -

24 EXAMINATION

1

2 BY MR. JANUSH:

8 Do you remember that?

9 A. Yes, I do.

10 Q. You can't really make that
11 statement, can you?

12 MR. GALIN: Objection.

13 BY MR. JANUSH:

14 Q. You are not with every rep
15 on every visit with every doctor, are
16 you?

17 A. I can clarify that the reps
18 are instructed per their overall job
19 responsibilities to leave a package
20 insert at the time of the visit.

21 Q. Okay. Sir, I'm going to
22 guess that you've never reviewed a large
23 Excel file of your sales representatives'
24 call notes while you were at Janssen

1 concerning Nucynta sales reps. Am I
2 right or wrong?

3 A. It would be fair to say that
4 I don't -- I have never reviewed call
5 notes for a sales force.

6 Q. Would -- would it surprise
7 you if call notes routinely demonstrate
8 that, the converse to your quote, that --
9 that reps fight for doctor time, may
10 barely get to see -- on some visits, may
11 barely get to see a doctor and on other
12 visits have an extensive discussion.
13 Would that surprise you or would you
14 expect that?

15 MR. GALIN: Objection to
16 form.

17 THE WITNESS: The examples
18 you've just mentioned, I think are
19 very commonplace in the
20 pharmaceutical industry. And they
21 are -- they represent the list of
22 potential outcomes during a visit.

23 BY MR. JANUSH:

24 Q. Right. And in -- and in

1 some instances, would it surprise you if
2 in many instances a rep who has a
3 discussion leaves behind a leave-behind
4 document, called a leave behind, that is
5 not actually a package insert?

6 A. It would be more accurate to
7 represent that many of the leave behinds
8 are actually -- have a package insert
9 affixed. And that's what allows the
10 package insert to accompany the actual
11 piece.

12 Q. Have you seen leave behinds
13 that actually don't have package inserts,
14 because those exist, right?

15 MR. GALIN: Objection to
16 form.

17 THE WITNESS: I think during
18 my -- my time in this industry,
19 it's pretty commonplace to affix a
20 PI to anything that's left behind
21 in the office.

22 MR. JANUSH: Move to strike,
23 nonresponsive.

24 BY MR. JANUSH:

1 Q. I'm not talking about what's
2 pretty common. I'm saying a package --
3 leave behinds that do not contain package
4 inserts exist, right?

5 A. During my time on the brand,
6 we did not, to my recollection, produce
7 leave behinds that did not have a package
8 insert affixed.

9 I cannot comment as to
10 whether they actually exist, any -- any
11 resource from any manufacturer has a
12 package insert affixed or not.

13 Q. And so when you testified
14 earlier that when a rep engages with an
15 office, they always leave a package
16 insert immediately before or after their
17 discussion with the physician, what you
18 meant to say is reps are instructed to
19 leave a package insert behind; is that
20 right?

21 A. I think that's fair to
22 characterize it as they are instructed to
23 leave a package insert.

24 Q. Earlier when your counsel

1 was questioning you, you were talking
2 about a PRC process and that all
3 materials, any content shared with the
4 customer, meaning a doctor, would go
5 through PRC. Do you remember that?

6 A. Yes.

7 Q. Do you sit on PRC, on the
8 PRC group?

9 A. As a member of a marketing
10 team, does not sit on PRC.

11 Q. Right. So you don't have
12 any firsthand knowledge of every single
13 communication that made it to a doctor
14 concerning whether such communications
15 went through PRC, correct?

16 MR. GALIN: Objection to
17 form.

18 THE WITNESS: I don't have
19 firsthand knowledge. And if -- if
20 I'm answering your question, I
21 don't have firsthand knowledge of
22 sitting through a PRC for every
23 possible piece that went to a
24 doctor.

1 BY MR. JANUSH:

2 Q. So you can't really make a
3 global statement that any communication
4 that a representative, a sales rep made
5 to a doctor was passed on by or approved
6 by the PRC, can you?

7 MR. GALIN: Objection to
8 form.

9 THE WITNESS: Could you just
10 repeat the --

11 BY MR. JANUSH:

12 Q. You can't really make a
13 global statement that any communication
14 that a sales representative made to a
15 doctor was approved by the PRC, can you?

16 A. I cannot make a
17 representation to -- that anything said
18 by a representative -- the words used by
19 a representative were, in fact, reviewed
20 by PRC.

21 What I can represent is that
22 any materials that a representative is
23 trained to use in communicating the
24 attributes of a product, are -- they are

1 reviewed by PRC.

2 Q. And by materials, you're
3 referring to, as an example, a
4 leave-behind, correct?

5 A. Yes.

6 Q. And by materials you're also
7 reviewing to -- referring to, excuse me,
8 the iPad sales aid that Janssen produced
9 for its sales reps to go through in a
10 live meeting with the doctor, the iPad
11 app on Nucynta; is that right?

12 A. That's right.

13 MR. JANUSH: I don't have
14 any further questions. However,
15 I'd like to note my objection on
16 the record concerning the failure
17 by defendant Janssen to produce
18 any personnel reviews of Mr. Lin
19 concerning his time working with
20 Nucynta whatsoever, particularly
21 considering Mr. Lin's testimony
22 that he was reviewed during each
23 year that he performed a role as a
24 director of marketing or director

1 of sales and marketing for the
2 pain group concerning the Nucynta
3 product.

4 MR. GALIN: I'll simply note
5 for the record that we've
6 responded to plaintiffs' and
7 Mr. Janush's letter in particular,
8 with our response to that.

9 And we'll let that letter
10 serve as our response at this
11 point.

12 THE VIDEOGRAPHER: No
13 further questions, right?

14 Okay. This marks the end of
15 today's deposition. The time is
16 6:43 p.m. Off the record.

17 (Excused.)

18 (The deposition concluded at
19 approximately 6:43 p.m.)
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CERTIFICATE

I HEREBY CERTIFY that the
witness was duly sworn by me and that the
deposition is a true record of the
testimony given by the witness.

It was requested before
completion of the deposition that the
witness, DAVID LIN, have the opportunity
to read and sign the deposition
transcript.

MICHELLE L. GRAY,
A Registered Professional
Reporter, Certified Shorthand
Reporter, Certified Realtime
Reporter and Notary Public
Dated: December 26, 2018

(The foregoing certification
of this transcript does not apply to any
reproduction of the same by any means,
unless under the direct control and/or
supervision of the certifying reporter.)

1 INSTRUCTIONS TO WITNESS

2

3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.

8 After doing so, please sign
9 the errata sheet and date it.

10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.

14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.

21

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24

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ACKNOWLEDGMENT OF DEPONENT

3

4

I, _____, do

5

hereby certify that I have read the

6

foregoing pages, 1 - 384, and that the

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same is a correct transcription of the

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answers given by me to the questions

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therein propounded, except for the

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corrections or changes in form or

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substance, if any, noted in the attached

12

Errata Sheet.

13

14

15

16

DAVID LIN

DATE

17

18

19

Subscribed and sworn

to before me this

20

_____ day of _____, 20____.

21

My commission expires: _____

22

23

Notary Public

24

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1	LAWYER'S NOTES		
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